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Cannabinoid inverse agonists would exert effects opposite those of THC and might thus cause appetite loss, short-term memory enhancement, nausea, or anxiety. Those effects could possibly be separated by molecular design, in which case inverse agonists might have some therapeutic value. One report has been published suggesting that the CB_1 receptor antagonist, SR141617A,[11] is an inverse agonist, and there will likely be others.

REGULATION OF AND MARKET OUTLOOK FOR MARIJUANA

Marijuana is not legally marketed in the United States.[12] No sponsor has ever sought marketing approval from the FDA for medical use of marijuana. One sponsor has an IND for a clinical safety study on HIV anorexia (D. Abrams, University of California at San Francisco, personal communication, 1998). Another has an IND pending for the treatment of migraine headaches (E. Russo, Western Montana Clinic, personal communication, 1998). Since 1970, marijuana's manufacture and distribution have been tightly restricted under the CSA, which places marijuana in Schedule I, which is reserved for drugs or other substances with "a high potential for abuse," "no currently accepted medical use," and "lack of accepted safety for use . . . under medical supervision" (21 U.S.C. § 812 (b)(1)).

Marijuana has remained in Schedule I despite persistent efforts at rescheduling since the 1970s by advocacy groups, such as NORML. Through petitions to the DEA, advocacy groups contend that marijuana does not fit the legal criteria for a Schedule I substance, owing to its purported medical uses and lack of high abuse liability.[3,4,48] Another rescheduling petition, which was filed in 1995, is being evaluated by the FDA and DEA.

Availability for Research

To use marijuana for research purposes, researchers must register with the DEA, as well as adhere to other relevant requirements of the CSA and other federal statutes, such as the FD&C act. The National Institute on Drug Abuse (NIDA), one of the institutes of NIH, is the only organization in the United States licensed by the DEA to manufacture and distribute marijuana for research purposes. NIDA performs this function under its Drug Supply Program.[14] Through this program, NIDA arranges for marijuana to be grown and processed through contracts with two organizations: the University of Mississippi and the Research Triangle Institute. The University of Mississippi grows, harvests, and dries marijuana; and the institute processes it into cigarettes. A researcher can obtain marijuana free of charge from NIDA through an NIH-approved research grant to investigate marijuana, or through a separate protocol review.[39] Research grant approvals are handled through the conventional NIH peer review process for extramural research, a highly competitive process with a success rate in 1997 of 32% of approved NIDA grants.[41]

Through the separate protocol review, in which a researcher funds research independently of an NIH grant, NIDA submits the researcher's protocol to several external reviewers who evaluate the protocol on the basis of scientific merit and relevance to the mission of NIDA and NIH.

Through those two avenues marijuana has been supplied to several research groups--most of those that apply. While there has been much discussion of NIDA's alleged failure to supply marijuana for research purposes, we are unaware of recent cases in which they failed to supply marijuana to an investigator with an NIH-approved grant for research on marijuana. Donald Abrams's difficulty in obtaining research funding and marijuana from NIDA has been much discussed,[2] but the case of a single individual should not be presumed to be representative of the community of marijuana researchers. Failure of investigators who apply to NIH for marijuana research grants to receive funding is hardly exceptional: in 1998 less than 25% of *all* first time investigator-initiated grant applications (known as RO1s) to the NIH were funded.[35]

To import marijuana under the CSA for research purposes, the procedures are more complex. Under DEA regulations, marijuana can be imported, provided that the researcher is registered with the DEA, has approval for marijuana research (21 CFR § 1301.11, .13, and .18), and has a DEA-approved permit for importation (21 CFR § 1312.11, .12, and .13), and that the exporter in the foreign country has appropriate authorization by the country of exportation. Importation would enable U.S. researchers to conduct research on marijuana grown by HortaPharm, a company that has developed unique strains of marijuana. However, no U.S. researcher has imported HortaPharm's marijuana because Dutch authorities have refused to issue an export permit, despite the issuance of an import permit by the DEA (D. Pate, HortaPharm, personal communication, 1998).[15]

HortaPharm, which is in the Netherlands, grows marijuana as a raw material for the manufacture of pharmaceuticals. Through selective breeding and controlled production, HortaPharm has developed marijuana strains that feature single cannabinoids, such as THC or cannabidiol. The plants contain a consistently "clean" phytochemical profile and a higher concentration of THC (16%) or other desired cannabinoids than seized marijuana. Marijuana seized in the United States in 1996 had a THC content averaging about 5%.[16] Consistency of THC content is desirable because it overcomes the natural variability due to latitude, weather, and soil conditions. Product consistency is a basic tenet of pharmacology because it enables standardized dosing for regulatory and treatment purposes.

The difficulties of conducting research on marijuana were noted in the 1997 NIH report[40] that recommended that NIH facilitate clinical research by developing a centralized mechanism to promote design, approval, and conduct of clinical trials.

Regulatory Hurdles to Market

For marijuana to be marketed legally in the United States, a sponsor with sufficient resources would be obliged to satisfy the regulatory requirements of both the FD&C act and the CSA.

Under the FD&C act, a botanical product like marijuana *theoretically* might be marketed in oral form as a dietary supplement;[16] however, as a practical matter, only a new drug approval is likely to satisfy the provisions of the CSA, which require prescribing and distribution controls on drugs of abuse that also have an "accepted medical use." (The final paragraphs of this section clarify the criteria for "accepted medical use.")

Bringing marijuana to market as a new drug is uncharted terrain. The route is fraught with uncertainty for at least three pharmacological reasons: marijuana is a botanical product, it is smoked, and it is a drug with abuse potential. In general, botanical products are inherently more difficult to bring to market than are single chemical entities because they are complex mixtures of active and inactive ingredients. Concerns arise about product consistency, potency of the active ingredients, contamination, and stability of both active and inactive ingredients over time. These are among the concerns that a sponsor would have to overcome to meet the requirements for an NDA, especially those related to safety and to chemistry, manufacturing, and control.

A handful of botanical preparations are on the market, but none received formal approval as a new drug by today's standards of safety and efficacy (FDA, Center for Drug Evaluation and Research, personal communication, 1998). The three marketed botanical preparations are older drugs that came to market years before safety and efficacy studies were required by legislative amendments in 1938 and 1962, respectively. One of the botanical preparations is the prescription product digitalis. Because it came to market before 1938, it is available today, having been "grandfathered" under the law; but it does not necessarily meet contemporary standards for safety and effectiveness.[20] Two other botanical preparations, psyllium and senna, came to market between 1938 and 1962. Drugs entering the market during that period were later required to be evaluated by the FDA in what is known as the over-the-counter drug review process,[20] through which psyllium and senna were found to be generally recognized as safe and effective and so were allowed to remain on the market as over-the-counter drugs.[17] Although no botanical preparations have been approved as new drugs, it is important to point out that a number of individual plant constituents, either extracted or synthesized *de novo*, have been approved (for example, taxol and morphine). But these drug approvals were for single constituents rather than botanical preparations themselves. The FDA is developing guidance for industry to explain how botanicals are reviewed as new drugs, but the final document might not be available before 1999.

That marijuana is smoked might pose an even greater regulatory challenge. The risks associated with smoking marijuana are described in chapter 2. The FDA would have to weigh those risks with marijuana's

therapeutic benefits to arrive at a judgment about whether a sponsor's NDA for marijuana met the requirements for safety and efficacy under the FD&C act. Marijuana delivered in a novel way that avoids smoking would overcome some, but not all, of the regulatory concerns. Vaporization devices that permit inhalation of plant cannabinoids without the carcinogenic combustion products found in smoke are under development by several groups; such devices would also require regulatory review by the FDA.

The regulatory hurdles to market posed by the CSA are formidable but not insurmountable. If marijuana received market approval as a drug by the FDA, it would most likely be rescheduled under the CSA, as was the case for dronabinol. That is because a new drug approval satisfies the "accepted medical use" requirement under the CSA for manufacture and distribution in commerce.[13] But a new drug approval is not the *only* means to reschedule marijuana under the CSA.[14] For years advocates for rescheduling have argued that marijuana does enjoy "accepted medical use," even in the absence of a new drug approval. Although advocates have been unsuccessful in rescheduling efforts, their actions prompted the DEA to specify the criteria by which it would determine whether a substance had "accepted medical use." In the DEA's 1992 denial of a rescheduling petition, it listed these elements as constituting "accepted medical use": the drug's chemistry must be known and reproducible, there must be adequate safety studies, there must be adequate and well-controlled studies proving efficacy, the drug must be accepted by qualified experts, and the scientific evidence must be widely available.[14]

Assuming that all of those criteria were satisfied, marijuana could be rescheduled--but into which schedule? The level of scheduling would be dictated primarily by a medical and scientific recommendation to the DEA made by the secretary of DHHS.[18] As noted earlier, this recommendation is determined by the five scheduling criteria listed in the CSA. However, scheduling in a category less restrictive than Schedule II might be prohibited by international treaty obligations. The Single Convention on Narcotic Drugs, a treaty ratified by the United States in 1967, restricts scheduling of the plant and its resin to at least Schedule II (the more restrictive Schedule I is another option).[13]

Market Outlook

The market outlook for the development of marijuana as a new drug, on the basis of the foregoing analysis, is not favorable, for a host of scientific, regulatory, and commercial reasons. From a scientific point of view, research is difficult because of the rigors of obtaining an adequate supply of legal, standardized marijuana for study. Further scientific hurdles are related to satisfying the exacting requirements for FDA approval of a new drug. The hurdles are even more exacting for a botanical product because of the inherent problems with, for example, purity and consistency. Finally, the health risks associated with smoking pose another barrier to FDA approval unless a new smoke-free route of administration is demonstrated

to be safe. Depending on the route of administration, an additional overlay of regulatory requirements might have to be satisfied.

From a commercial point of view, uncertainties abound. The often-cited cost of new drug development, about $200—$300 million, might not apply, but there are probably additional costs needed to satisfy the FDA's requirements for a botanical product. As noted above, no botanical products have ever been approved as new drugs by the FDA under today's stringent standards for safety and efficacy. Satisfying the legal requirements of the CSA also will add substantially to the cost of development. On the positive side, so much research already has been done that some development costs will be lower. The cost of bringing dronabinol to market, for example, was reduced dramatically as a result of clinical trials supported with government funding. Nevertheless, it is impossible to estimate the cost of developing marijuana as a new drug. Estimating return on investment is similarly difficult. A full-fledged market analysis would be required for the indication being sought. Such an analysis would take into account the market limitations resulting from drug scheduling restrictions, stigma, and patentability.

The plant does not constitute patentable subject matter under U.S. patent law because it is unaltered from what is found in nature. So-called products of nature are not generally patentable.[28] New marijuana strains, however, could be patentable in the United States under a product patent or a plant patent because they *are* altered from what is found in nature. (A product patent prohibits others from manufacturing, using, or selling each strain for 20 years; a plant patent carries somewhat less protection.) HortaPharm has not yet sought any type of patent for its marijuana strains in the United States, but it has received approval for a plant registration in Europe (David Watson, HortaPharm, personal communication, 1998).

In short, development of the marijuana plant is beset by substantial scientific, regulatory, and commercial obstacles and uncertainties. The prospects for its development as a new drug are unfavorable unless return on investment is not a driving force. It is noteworthy that no pharmaceutical firm has sought to bring it to market in the United States. The only interest in its development appears to be in England in a small pharmaceutical firm (see Boseley, 1998[10]) and in the United States among physicians without formal ties to pharmaceutical firms (D. Abrams, University of California at San Francisco, and E. Russo, Western Montana Clinic, personal communications, 1998).

CONCLUSIONS

Cannabinoids are an interesting group of compounds with potentially far-reaching therapeutic applications. There is a surge of scientific interest in their development as new drugs, but the road to market for any new drug is expensive, long, risky, and studded with scientific, regulatory, and commercial obstacles. Experience with the only approved cannabinoid, dronabinol, might not illuminate the pathway because of the government's heavy contribution to research and development, drona-binol's scheduling

history, and its small market.

There appear to be only two novel cannabinoids actively being developed for human use, but they have yet to be tested in humans in the United States. Their experience is likely to be more predictive of the marketing prospects for other cannabinoids. It is too early to forecast the prospects for cannabinoids, other than to note that their development at this point is considered to be especially risky, to judge by the paucity of products in development and the small size of the pharmaceutical firms sponsoring them.

The market outlook in the United States is distinctly unfavorable for the marijuana plant and for cannabinoids found in the plant. Commercial interest in bringing them to market appears nonexistent. Cannabinoids in the plant are automatically placed in the most restrictive schedule of the Controlled Substances Act, and this is a substantial deterrent to development. Not only is the plant itself subject to the same scheduling strictures as are individual plant cannabinoids, but development of marijuana also is encumbered by a constellation of scientific, regulatory, and commercial impediments to availability.

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Notes

[1] FDA policies for off-label use are being transformed as a result of the Food and Drug Administration Modernization Act of 1997. The FDA recently promulgated new rules to give manufacturers greater flexibility to disseminate information about off-label uses (FDA, 1998b[24a]). As of this writing, however, court decisions have left the status of the new rules somewhat unclear.

[2] The FDA can grant orphan designation to a drug intended for a condition that affects a larger population if the manufacturer's estimated expenses are unlikely to be recovered by sales in the United States (Public Law 98-551).

[3] Marijuana cigarettes were available under a special FDA-sponsored Compassionate Investigational New Drug Program for desperately ill patients until March 1992, when the program was closed to new participants.[45]

[4] The FDA and the National Institute of Drug Abuse, two agencies of DHHS, work jointly to develop the medical and scientific analysis that is forwarded to the secretary, who makes recommendation to the administrator of the DEA (DEA, 1998[15]).

[5] Under the CSA, "the recommendations of the Secretary to the Attorney General shall be binding on the Attorney General as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Attorney General shall not control the drug or other substance" (21 U.S.C. § 811 (b)).

[6] Technically, the CSA and the regulations use the term "tetrahydrocannabinols."

[7] The only cannabinoid licensed outside the United States is nabilone (Cesamet), which is an analogue of THC available in the United Kingdom for the management of nausea and vomiting associated with cancer chemotherapy (Pertwee, 1997).[46]

[8] A use patent--also known as a process patent--accords protection for a method of using a composition or compound. A use patent is not considered as strong as a product patent, which prohibits others from manufacturing, using, or selling the product for all uses, rather than for the specific use defined in a use patent.

[9] The DEA did not provide an estimate of the weight of marijuana per bag.

Information about the existence of an IND is proprietary; it can be confirmed only by the manufacturer, not the FDA.

[11] Discontinued: levonantradol, nabitan, nantradol, and pravadoline. Undeveloped: CP-47497 and CP-55244.

[12] As a result of the FDA's approval of an NDA, the drug would be, at a minimum, rescheduled in Schedule II. Depending on abuse liability data supplied by the manufacturer and the FDA's recommendation, the drug could be moved to a less restrictive schedule or be descheduled.

[13] Under the CSA, its only legal use is in research under strictly defined conditions.

[14] This is also the program through which several patients receive marijuana under a compassionate use program monitored by the FDA. For history and information on this effort, see Randall (1993).[48]

[15] It might eventually be possible to import HortaPharm's marijuana from England, where HortaPharm is growing its marijuana strains for research use in clinical trials for multiple sclerosis (Boseley, 1998).[49] England, as the country of origin, would have to provide appropriate authorization for export of the strains to the United States. Permission to export for research purposes is part of the basis for HortaPharm's participation in this project with GW Pharmaceuticals through a special set of licenses with the British Home Office (David Pate, HortaPharm, personal communication, 1998).

[16] Inhaled products may not lawfully be marketed as dietary supplements.

[17] Over-the-counter monographs for these products have been issued as tentative final monographs (proposed rules) but have not yet been issued in final form as final rules (FDA, Center for Drug Evaluation and Research, personal communication, 1998).

[18] At present, there is no practical mechanism for generating such a recommendation outside the new drug approval process, although such a mechanism could, theoretically, be developed.[19]

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Appendix A

Individuals and Organizations That Spoke or Wrote to the Institute of Medicine About Marijuana and Medicine

Donald I. Abrams
University of California at San Francisco

Jill Aguilera
Colorado Federation of Parents

William F. Alden
D.A.R.E. America

Roger D. Anderson
Anderson Clinical Research

M. Douglas Anglin
UCLA Drug Abuse Research Center

Dave Baleria
Jackson County Sheriff's Office

Joe Barker

Frank Bartosic
Minister of Universal Life Church

Dana Beal
Cures Not Wars

J. Bellam
Center for Drug Information

Sandra S. Bennett
Northwest Center for Health and Safety

Anna T. Boyce
California Senior Legislature (Prop 215)

William Britt

Richard Brookhiser
National Review

Ronald Brooks
California Narcotic Officers Association

Bonnie Broussard
L.A. Takes a Stand, Inc.

Al Byrne
Patients Out of Time

Marvin Edward Chavez, Sr.
O.C. Patient-Doctor-Nurse Support Group Cannabis Co-Op

Steven Childers
Bowman Gray School of Medicine
Wake Forest University

Barb Christensen
Prevention Partners

Gale Cincotta
National People's Action

Carol Coburn
Prevention Partners

Chris Conrad
Author of *Hemp for Health*

Paul Consroe
University of Arizona

J. Richard Crout
Private Consultant

Judy Cushing
Oregon Partnership, National Family Partnership

John De Miranda
Peninsula Health Concepts

Mahendra Dedhiya
Roxane Laboratories, Inc.

Robert Deitch
Cannabis Freedom Fund

Philip Diaz
Physicians for Prevention

Stephen L. Dilts

American Academy of Addiction Psychiatry

Rick Doblin
MAPS and Kennedy School of Government

Del Dolton

Barbara Douglass

Drug-Free Youth--USA

Robert Dudley
UNIMED

Victoria Duran
National Parents and Teachers Association

David Edwards

Edward Ehman
Certified Prevention Specialist

Mahmoud ElSohly
University of Mississippi

Mouncey Ferguson

Howard L. Fields
University of California at San Francisco

Jody Fitt

Richard W. Foltin
Columbia University

Etienne Fontan
Cannabis Alliance of Veterans, 1st CAV

Meg Foster

Phyllis Gardner
ALZA Corporation

Charles V. Giannasio
American Academy of Addiction Psychiatry

Dale Gieringer
California NORML, Friends of 215

Mark Gold
University of Florida Brain Institute

Richard Gralla
OCHSNER Cancer Institute

Linda Hall

Pride, Omaha, Inc.

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UNITED STATES DEPARTMENT OF JUSTICE
Drug Enforcement Administration

In The Matter Of)
) Docket No. 86-22
MARIJUANA RESCHEDULING PETITION)

OPINION AND RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW AND DECISION OF Administrative LAW JUDGE.

FRANCIS L. YOUNG, Administrative Law Judge

DATED: SEP 6 1988

UNITED STATES DEPARTMENT OF JUSTICE
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FRANCIS L. YOUNG, Administrative Law Judge

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DATED: SEP 6 1988

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UNITED STATES DEPARTMENT OF JUSTICE
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In The Matter Of)
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OPINION AND RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW AND DECISION OF ADMINISTRATIVE LAW JUDGE.

I.

INTRODUCTION

This is a rulemaking pursuant to the Administrative Procedure Act, 5 U.S.C. § 551, et seq., to determine whether the marijuana plant (Cannabis sativa L) considered as a whole may lawfully be transferred from Schedule I to Schedule II of the schedules established by the Controlled Substances Act (the Act), 21 U.S.C. § 801, et seq. None of the parties is seeking to "legalize" marijuana generally or for recreational purposes. Placement in Schedule II would mean, essentially, that physicians in the United States would not violate Federal law by prescribing marijuana for their patients for legitimate therapeutic purposes. It is contrary to Federal law for physicians to do this as long as marijuana remains in Schedule I. This proceeding had its origins on May 18, 1972 when the National Organization for the Reform of Marijuana Laws (NORML) and two other groups submitted a petition to the Bureau of Narcotics and Dangerous Drugs (BNDD) [footnote 1], predecessor

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1 The powers and authority granted by the Act to the Attorney General were delegated to the Director of BNDD and subsequently to the Administrator of DEA. 28 C.F.R. § 0.100, et seq.

agency to the Drug Enforcement Administration (DEA or the Agency), asking that marijuana be removed from Schedule I and freed of all controls entirely, or be transferred from Schedule I to Schedule V where it would be subject to only minimal controls. The Act by its terms had placed marijuana in Schedule I thereby declaring, as a matter of law that it had no legitimate use in therapy in the United States and subjecting the substance to the strictest level of controls. The Act had been in effect for just over one year when NORML submitted its 1972 petition.

On September 1, 1972 the Director of BNDD announced his refusal to accept the petition for filing, stating that he was not authorized to institute proceedings for the action requested because of the provisions of the Single Convention on Narcotic Drugs, 1961. NORML appealed this action to the United States Court of Appeals for the District of Columbia Circuit. The court held that the Director had erred in rejecting the petition without "a reflective consideration and analysis," observing that the Director's refusal "was not the kind of agency action that promoted the kind of interchange and refinement of views that is the lifeblood of a sound administrative process." NORML v. Ingersoll, 162 U.S. App. D.C. 67, 497 F.2d 654, 659 (1974). The court remanded the matter in January 1974 for further proceedings not inconsistent with its

opinion, "to be denominated a consideration on the merits." Id.

A three-day hearing was held at DEA [footnote 2] by Administrative Law Judge Lewis Parker in January 1975. The judge found in NORML's favor on several issues but the Acting Administrator of DEA entered a final order denying NORML's petition "in all respects." NORML again petitioned the court for review. Finding fault

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2 DEA became the successor agency to BNDD in a reorganization carried out pursuant to Reorganization Plan No. 2 of 1973, eff. July 1, 1973. 38 Fed Reg. 15932 (1973).

with DEA's final order the court again remanded for further proceedings not inconsistent with its opinion. NORML v. DEA, 182 U.S. App. D.C. 114, 559 F.2d 735 (1977). The Court directed the then-Acting Administrator of DEA to refer NORML's petition to the Secretary of the Department of Health, Education and Welfare (HEW) for findings and, thereafter, to comply with the rulemaking procedures outlined in the Act at 21 U.S.C. § 811 (a) and (b).

On remand the Administrator of DEA referred NORML's petition to HEW for scientific and medical evaluation. On June 4, 1979 the Secretary of HEW advised the Administrator of the results of the HEW evaluation and recommended that marijuana remain in Schedule I. Without holding any further hearing the Administrator of DEA proceeded to issue a final order ten days later denying NORML's petition and declining to initiate proceedings to transfer marijuana from Schedule I. 44 Fed. Reg. 36123 (1979). NORML went back to the Court of Appeals.

When the case was called for oral argument there was discussion of the then-present status of the matter. DEA had moved for a partial remand. The court found that "reconsideration of all the issues in this case would be appropriate" and again remanded it to DEA, observing: "We regrettably find it necessary to remind respondents [DEA and HEW] of an agency's obligation on remand not to 'do anything which is contrary to either the letter or spirit of the mandate construed in the light of the opinion of [the] court deciding the case.'" (Citations omitted.) NORML v. DEA, et al., No. 79.1660, United States Court of Appeals for the District of Columbia Circuit, unpublished order filed October 16, 1980. DEA was directed to refer all the substances at issue to the Department of Health and Human Services (HHS), successor agency to HEW, for scien-

tific and medical findings and recommendations on scheduling. DEA did so and HHS has responded. In a letter dated April 1, 1986 the then-Acting Deputy Administrator of DEA requested this administrative law judge to commence hearing procedures as to the proposed rescheduling of marijuana and its components.

After the Judge conferred with counsel for NORML and DEA, a notice was published in the Federal Register on June 24, 1986 announcing that hearings would be held on NORML's petition for the rescheduling of marijuana and its components commencing on August 21, 1986 and giving any interested person who desired to participate the opportunity to do so. 51 Fed. Reg. 22946 (1986).

Of the three original petitioning organizations in 1972 only NORML is a party to the present proceeding. In addition the following entities responded to the Federal Register notice and have become parties, participating to varying degrees: the Alliance for Cannabis Therapeutics (ACT), Cannabis Corporation of America (CCA) and Carl Eric Olsen, all seeking transfer of marijuana to Schedule II; the Agency, National Federation of Parents for Drug free Youth (NFP) and the International Association of Chiefs of Police (IACP), all contending that marijuana should remain in Schedule I.

Preliminary prehearing sessions were held on August 21 and December 5, 1986 and on February 20, 1987. [footnote 3] During the preliminary stages, on January 20, 1987, NORML filed an amended petition for rescheduling. This new petition abandoned NORML's previous requests for the complete descheduling of marijuana or rescheduling to Schedule V. It asks only that marijuana be placed in Schedule II.

At a prehearing conference on February 20, 1987 this amended petition was

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3 Transcripts of these three preliminary prehearing sessions are included in the record.

discuss. [footnote 4] All Parties present stipulated, for the purpose of this proceeding, that marijuana has a high potential for abuse and that abuse of the marijuana plant may lead to severe psychological or physical dependence. They then agreed that the principal issue in this proceeding would be stated thus:

> Whether the marijuana plant, considered as a whole, [footnote 5] may

4 The transcript of this prehearing conference and of the subsequent hearing session comprise 15 volumes numbered as follows:

Vol. I - Prehearing Conference, October 16, 1987

Vol. II - Cross Examination, November 19, 1987

Vol. III - Cross Examination, December 8, 1987

Vol. IV - Cross Examination, December 9, 1987

Vol. V - Cross Examination, January 5, 1988

Vol. VI - Cross Examination, January 6, 1988

Vol. VII - Cross Examination, January 7, 1988

Vol. VIII - Cross Examination, January 26, 1988

Vol. IX - Cross Examination, January 27, 1988

Vol. X - Cross Examination, January 28, 1988

Vol. XI - Cross Examination, January 29, 1988

Vol. XII - Cross Examination, February 2, 1988

Vol. XIII - Cross Examination, February 4, 1988

Vol. XIV - Cross Examination, February 5, 1988

Vol. XV - Oral Argument, June 10, 1988

Pages of the transcript are cited herein by volume and page, e.g. "Tr. V-96"; "G-" identifies an Agency exhibit.

5 Throughout this opinion the term marijuana" refers to "the marijuana plant, consider as a whole".

lawfully be transferred from Schedule I to Schedule II of the schedules established by the Controlled Substances Act.

Two subsidiary issues were agreed on, as follows:

1. Whether the marijuana plant has a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions.

2. Whether there is a lack of accepted safety for use of the marijuana plant under medical supervision.

As stated above, the parties favoring transfer from Schedule I to Schedule II are NORML, ACT, CCA and Carl Eric Olsen. Those favoring retaining marijuana in Schedule I are the Agency, NFP and IACP.

During the Spring and Summer of 1987 the parties identified their witnesses and put the direct examination testimony of each witness in writing in affidavit form. Copies of these affidavits were exchanged. Similarly, the parties assembled their proposed exhibits and exchanged copies. Opportunity was provided for each party to submit objections to the direct examination testimony and exhibits proffered by the others. The objections submitted were considered by the administrative law judge and ruled on. The testimony and exhibits not excluded were admitted into the record. Thereafter hearing sessions were held at which witnesses were subjected to cross-examination. These sessions were held in New Orleans, Louisiana on November 18 and 19, 1987; in San Francisco, California on December 8 and 9, 1987; and in Washington, D.C. on January 5 through 8 and 26 through 29, and on February 2, 4 and 5, 1988. The parties have submitted proposed findings and conclusions and briefs. Oral arguments were heard by the judge on June 10, 1988 in Washington.

II.

RECOMMENDED RULING

It is recommended that the proposed findings and conclusions submitted by the parties to the administrative law judge be rejected by the Administrator except to the extent they are included in those hereinafter set forth; for the reason that they are irrelevant or unduly repetitious or not supported by a preponderance of the evidence. 21 C.F.R. § 1316.65(a)(1).

III.

ISSUES

As noted above, the agreed issues are as follows:

Principle issue:

Whether the marijuana plant, considered as a whole, may lawfully be transferred from Schedule I to Schedule II of the schedules established by the Controlled Substances Act.

Subsidiary issues:

1. Whether the marijuana plant has a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions.

2. Whether there is a lack of accepted safety for use of the marijuana plant under medical supervision.

IV.

STATUTORY REQUIREMENTS FOR SCHEDULING

The Act provides (21 U.S.C. § 812(b)) that a drug or other substance may not be placed in any schedule unless certain specified findings are made with respect to it. The findings required for Schedule I and Schedule II are as follows:

Schedule I. -

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Schedule II. -

(A) The drug or other substance has a high potential for abuse.

CORRECTION

THE FOLLOWING DOCUMENT(S)
HAVE BEEN REFILMED TO
ASSURE LEGIBILITY OR PAGINATION

As noted above, the agreed issues are as follows:

Principle issue:

Whether the marijuana plant, considered as a whole, may lawfully be transferred from Schedule I to Schedule II of the schedules established by the Controlled Substances Act.

Subsidiary issues:

1. Whether the marijuana plant has a currently accepted medical use in treatment in the United States, or a currently accepted medical use with severe restrictions.

2. Whether there is a lack of accepted safety for use of the marijuana plant under medical supervision.

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Schedule I. -

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Schedule II. -

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances [sic] may lead to severe psychological or physical dependence.

As noted above the parties have stipulated, for the purpose of this proceeding, that marijuana has a high potential for abuse and that abuse of it may lead to severe psychological or physical dependence. Thus the dispute between the two sides in this proceeding is narrowed to whether or not marijuana has a currently accepted medical use in treatment in the United States, and whether or not there is a lack of accepted safety for use of marijuana under medical supervision.

The issues as framed here contemplate marijuana's being placed only in

Schedule I or Schedule II. The criteria for placement in any of the other three schedules established by the Act are irrelevant to this proceeding.

V.

ACCEPTED MEDICAL USE IN TREATMENT

- CHEMOTHERAPY

With respect to whether or not marijuana has a "currently accepted medical use in treatment in the United States" for chemotherapy patients, the record shows the following facts to be uncontroverted.

Findings Of Fact

1. One of the most serious problems experienced by cancer patients undergoing chemotherapy for their cancer is severe nausea and vomiting caused by their reaction to the toxic (poisonous) chemicals administered to them in the course of this treatment. This nausea and vomiting at times becomes life threatening. The therapy itself creates a tremendous strain on the body. Some patients cannot tolerate the severe nausea and vomiting and discontinue treatment. Beginning in the 1970's

there was considerable doctor-to-doctor communication in the United States concerning patients known by their doctors to be surreptitiously using marijuana with notable success to overcome or lessen their nausea and vomiting.

2. Young patients generally achieve better control over nausea and vomiting from smoking marijuana than do older patients, particularly when the older patient has not been provided with detailed information on how to smoke marijuana.

3. Marijuana cigarettes in many cases are superior to synthetic THC capsules in reducing chemotherapy-induced nausea and vomiting. Marijuana

cigarettes have an important, clear advantage over synthetic THC capsules in that the natural marijuana is inhaled and generally takes effect more quickly than the synthetic capsule which is ingested and must be processed through the digestive system before it takes effect.

4. Attempting to orally administer the synthetic THC capsule to a vomiting patient presents obvious problems - it is vomited right back up before it can have any effect.

5. Many physicians, some engaged in medical practice and some teaching in medical schools, have accepted smoking marijuana as effective in controlling or reducing the severe nausea and vomiting (emesis) experienced by some cancer patients undergoing chemotherapy for cancer.

6. Such physicians include board-certified internists, oncologists and psychiatrists. (Oncology is the treatment of cancer through the use of highly toxic chemicals, or chemotherapy.)

7. Doctors who have come to accept the usefulness of marijuana in controlling or reducing emesis resulting from chemotherapy have dose so as the result of reading reports of studies and anecdotal reports in their professional literature, and as the result of observing patients and listening to reports directly from patients.

8. Some cancer patients who have acknowledged to doctors that they smoke marijuana for emesis control have indicated in their discussions that, although they may have first smoked marijuana recreationally, they accidentally found that doing so helped reduce the emesis resulting from their chemotherapy. They consistently indicated that they felt better and got symptomatic relief from the intense nausea

and vomiting caused by the chemotherapy. These patients

were no longer simply getting high, but were engaged in medically treating their illness, albeit with an illegal substance. Other chemotherapy patients began smoking marijuana to control their emesis only after hearing reports that the practice had proven helpful to others. Such patients had not smoked marijuana recreationally.

9. This successful use of marijuana has given many cancer chemotherapy patients a much more positive outlook on their overall treatment, once they were relieved of the debilitating, exhausting and extremely unpleasant nausea and vomiting previously resulting from their chemotherapy treatment.

10. In about December 1977 the previously underground patient practice of using marijuana to control emesis burst into the public media in New Mexico when a young cancer patient, Lynn Pearson, began publicly to discuss his use of marijuana. Mr. Pearson besought the New Mexico legislature to pass legislation making marijuana available legally to seriously ill patients whom it might help. As a result, professionals in the public health sector in New Mexico more closely examined how marijuana might be made legally available to assist in meeting what now openly appeared to be a widely recognized patient need.

11. In many cases doctors have found that, in addition to suppressing nausea and vomiting, smoking marijuana is a highly successful appetite stimulant. The importance of appetite stimulation in cancer therapy cannot be overstated. Patients receiving chemotherapy often lose tremendous amounts of weight. They endanger their lives because they lose interest in food and in eating. The resulting sharp reduction in weight may well affect their prognosis. Marijuana smoking induces some patients to eat. The benefits are obvious, doctors have found. There is no significant loss of weight. Some patients will gain weight.

This allows them to retain strength and makes them better able to fight the cancer. Psychologically, patients who can continue to eat even while receiving chemotherapy maintain a balanced outlook and are better able to cope with their disease and its treatment, doctors have found.

12. Synthetic anti-emetic agents have been in existence and utilized for a number of years. Since about 1980 some new synthetic agents have been developed which appear to be more effective in

controlling and reducing chemotherapy-induced nausea and vomiting than were some of those available in the 1970's. But marijuana still is found more effective for this purpose in some people than any of the synthetic agents, even the newer ones.

13. By the late 1970's in the Washington, D.C. area there was a growing recognition among health care professionals and the public that marijuana had therapeutic value in reducing the adverse effects of some chemotherapy treatments. With this increasing public awareness came increasing pressure from patients on doctors for information about marijuana and its therapeutic uses. Many patients moved into forms of unsupervised self-treatment. While such self-treatment often proved very effective, it has certain hazards, ranging from arrest for purchase or use of an illegal drug to possibly serious medical complications from contaminated sources or adulterated materials. Yet, some patients are willing to run these risks to obtain relief from the debilitating nausea and vomiting caused by their chemotherapy treatments.

14. Every oncologist known to one Washington, D.C. practicing internist and board-certified oncologist has had patients who used marijuana with great success to prevent or diminish chemotherapy-induced nausea and vomiting. Chemotherapy patients reporting directly to that Washington doctor that they

have smoked marijuana medicinally vomit less and eat better than patients who do not smoke it. By gaining control over their severe nausea and vomiting these patients undergo a change of mood and have a better mental outlook than patients who, using the standard anti-emetic drugs, are unable to gain such control.

15. The vomiting induced by chemotherapeutic drugs may last up to four days following the chemotherapy treatment. The vomiting can be intense, protracted and, in some instances, is unendurable. The nausea which follows such vomiting is also deep and prolonged. Nausea may prevent a patient from taking regular food or even much water for periods of weeks at a time.

16. Nausea and vomiting of this severity degrades the quality of life for these patients, weakening them physically, and destroying the will to fight the cancer. A desire to end the chemotherapy treatment in order to escape the emesis can supersede the will to live. Thus the emesis, itself, can truly be considered a life-threatening consequence of many cancer treatments. Doctors have known such cases to occur. Doctors have known other cases where marijuana smoking has enabled the patient to

endure, and thus continue, chemotherapy treatments with the result that the cancer has gone into remission and the patient has returned to a full, active satisfying life.

17. In San Francisco chemotherapy patients were surreptitiously using marijuana to control emesis by the early 1970's. By 1976 virtually every young cancer patient receiving chemotherapy at the University of California in San Francisco was using marijuana to control emesis with great success. The use of marijuana for this purpose had become generally accepted by the patients and increasingly by their physicians as a valid and effective form of treatment. This was particularly true for younger cancer patients, somewhat less common for

older ones. By 1979 about 25% to 30% of the patients seen by one San Francisco oncologist were using marijuana to control emesis, about 45 to 50 patients per year. Such percentages and numbers vary from city to city. A doctor in Kansas City who sees about 150 to 200 new cancer patients per year found that over the 15 years 1972 to 1987 about 5% of the patients he saw, or a total of about 75, used marijuana medicinally.

18. By 1987 marijuana no longer generated the intense interest in the world of oncology that it had previously, but it remains a viable tool, commonly employed, in the medical treatment of chemotherapy patients. There has evolved an unwritten but accepted standard of treatment within the community of oncologists in the San Francisco, California area which readily accepts the use of marijuana.

19. As of the Spring of 1987 in the San Francisco area, patients receiving chemotherapy commonly smoked marijuana in hospitals during their treatments. This in-hospital use, which takes place in rooms behind closed doors, does not bother staff, is expected by physicians and welcomed by nurses who, instead of having to run back and forth with containers of vomit, can treat patients whose emesis is better controlled than it would be without marijuana. Medical institutions in the Bay area where use of marijuana obtained on the streets is quite common, although discrete, include the University of California at San Francisco Hospital, the Mount Zion Hospital and the Franklin Hospital. In effect, marijuana is readily accepted throughout the oncologic community in the bay area for its benefits in connection with chemotherapy. The same situation exists in other large metropolitan areas of the United States.

20. About 50% of the patients seen by one San Francisco oncologist

Click here for Part 2

during the year 1987 were smoking marijuana medicinally. This is about 90 to 95 individuals. This number is higher than during the previous ten years due to the nature of this physician's practice which includes patients from the "tenderloin" area of San Francisco, many of whom are suffering from AIDS-related lymphosarcoma. These patients smoke marijuana to control their nausea and vomiting, not to "get high." They self-titrate, i.e., smoke the marijuana only as long as needed to overcome the nausea, to prevent vomiting.

21. The State of New Mexico set up a program in 1978 to make marijuana available to cancer patients pursuant to an act of the State legislature. The legislature had accepted marijuana as having medical use in treatment. It overwhelmingly passed this legislation so as to make marijuana available for use in therapy, not just for research. Marijuana and synthetic THC were given to patients, administered under medical supervision, to control or reduce emesis. The marijuana was in the form of cigarettes obtained from the Federal government. The program operated from 1979 until 1986, when funding for it was terminated by the State. During those seven years about 250 cancer patients in New Mexico received either marijuana cigarettes or THC. Twenty or 25 physicians in New Mexico sought and obtained marijuana cigarettes or THC for their cancer patients during that period. All of the oncologists in New Mexico accepted marijuana as effective for some of their patients. At least ten hospitals involved in this program in New Mexico, in which cancer patients smoked their marijuana cigarettes. The hospitals accepted this medicinal marijuana smoking by patients. Voluminous reports filed by the participating physicians make it clear that marijuana is a highly effective anti-emetic substance. It was found in the New Mexico program to be far superior to the best available conventional

anti-emetic drug, compazine, and clearly superior to synthetic THC pills. More than 90% of the patients who received marijuana within the New Mexico program reported significant or total relief from nausea and vomiting. Before the program began cancer patients were surreptitiously smoking marijuana in New Mexico to lessen or control their emesis resulting from chemotherapy treatments. They reported to physicians that it was successful for this purpose. Physicians were aware that this was going on.

22. In 1978 the Louisiana legislature became one of the first-State legislatures in the nation to recognize the efficacy of marijuana in controlling emesis by enacting legislation intended to make marijuana available by prescription for therapeutic use by chemotherapy patients. This enactment shows that there was widespread acceptance in Louisiana of the therapeutic value of marijuana. After a State Marijuana Prescription Review Board was established, pursuant to that legislation, it became apparent that, because of Federal restrictions, marijuana could be obtained legally only for use in cumbersome, formal research programs. Eventually a research program was entered into by the State, utilizing synthetic THC, but without much enthusiasm, since most professionals who had wanted to use marijuana clinically, to treat patients, had neither the time, resources nor inclination to get involved in this limited, formal study. The original purpose of the Louisiana legislation was frustrated by the Federal authorities. Some patients, who had hoped to obtain marijuana for medical use legally after enactment of the State legislation, went outside the law and obtained it illicitly. Some physicians in Louisiana accept marijuana as having a distinct medical value in the treatment of the nausea and vomiting associated with certain types of chemotherapy treatments.

23. In 1980 the State of Georgia enacted legislation authorizing a therapeutic research program for the evaluation of marijuana as a medically recognized therapeutic substance. Its enactment was supported by letters from a number of Georgia oncologist and other Georgia physician, including the Chief of oncology at Grady Hospital and staff oncologist at Emory University Medical Clinic. Sponsors of the legislation originally intended the enactment of a law making marijuana available for clinical, therapeutic use by patients. The bill was referred to as the "Marijuana-as-Medicine" bill. The final legislation was crafted, however, of necessity, merely to set up a research program in order to obtain marijuana from the one legitimate source available - the Federal Government, which would not make the substance available for any other purpose other than conducting a research program. The act was passed by an overwhelming majority in the lower house of the legislature and unanimously in the Senate. In January 1983 an evaluation of the program, which by then had 44 evaluable marijuana smoking patient-participants, accepted marijuana smoking as being an effective anti-emetic agent.

24. In Boston, Massachusetts in 1977 a nurse in a hospital suggested to a chemotherapy patient, suffering greatly from the therapy and at the point of refusing further treatment, that smoking marijuana

might help relieve his nausea and vomiting. The patient's doctor, when asked about it later, stated that many of his younger patients were smoking marijuana. Those who did so seemed to have less trouble with nausea and vomiting. The patient in question obtained some marijuana and smoked it, in the hospital, immediately before his next chemotherapy treatment. Doctors, nurses, and orderlies coming into the room as he finished smoking realized what the patient had been doing. None of them

made any comment. The marijuana was completely successful with this patient, who accepted it as effective in controlling his nausea and vomiting. Instead of being sick for weeks following chemotherapy, and having trouble going to work, as had been the case, the patient was ready to return to work 48 hours after that chemotherapy treatment. The patient thereafter always smoked marijuana, in the hospital, before chemotherapy. The doctors were aware of it, openly approved of it and encouraged him to continue. The patient resumed eating regular meals and regained lost eight, his mood improved markedly, he became more active and outgoing and began doing things together with his wife that he had not done since beginning chemotherapy.

25. During the remaining two years of this patient's life, before his cancer ended it, he came to know other cancer patients who were smoking marijuana to relieve the adverse effects of their chemotherapy. Most of these patients had learned about using marijuana medically from their doctors who, having accepted its effectiveness, subtly encouraged them to use it.

26. A Boston psychiatrist and professor, who travels about the country, has found a minor conspiracy to break the law among oncologists and nurses in every oncology center he has visited to let patients smoke marijuana before and during cancer chemotherapy. He has talked with dozens of these health care oncologists who encourage their patients to do this and who regard this as an accepted medical usage of marijuana. He has known nurses who have obtained marijuana for patients unable to obtain it for themselves.

27. A cancer patient residing in Beaverton, Michigan smoked marijuana medicinally in the nearby hospital where he was undergoing chemotherapy from early 1979 until he died of his cancer in October of that year. He smoked it in

his hospital room after his parents made arrangements with the hospital

for him to do so. Smoking marijuana controlled his post-chemotherapy nausea and vomiting, enabled him to eat regular-meals again with his family, and he became outgoing and talkative. His parents accepted his marijuana smoking as effective and helpful. Two clergymen, among others, brought marijuana to this patient's home. Many people at the hospital supported the patient's marijuana therapy, none doubted its helpfulness or discouraged it. This patient was asked for help by other patients. He taught some who lived nearby how to form the marijuana cigarettes and properly inhale the smoke to obtain relief from nausea and vomiting. When an article about this patient's smoking marijuana appeared in a local newspaper, he and his family heard from many other cancer patients who were doing the same. Most of them made an effort to inform their doctors. Most Physicians who knew their patients smoked marijuana medicinally approved, accepting marijuana's therapeutic helpfulness in reducing nausea and vomiting.

28. In October 1979 the Michigan legislature enacted legislation whose underlying purpose was to make marijuana available therapeutically for cancer patients and others. The State Senate passed the bill 29-5, the House of Representatives 100-0. In March 1982 the Michigan legislature passed a resolution asking the Federal Congress to try to alter Federal policies which prevent physicians from prescribing marijuana for legitimate medical applications and prohibit its use in medical treatments.

29. In Denver, Colorado a teenage cancer patient has been smoking marijuana to control nausea and vomiting since 1986. He has done this in his hospital room both before and after chemotherapy. His doctor and hospital staff know he does this. The doctor has stated that he would prescribe marijuana for

this patient if it were legal to do so. Other patients in the Denver area smoke marijuana for the same purpose. This patient's doctor, and nurses with whom he comes in contact, understand that cancer patients smoke marijuana to reduce or control emesis. They accept it.

30. In late 1980 a three year old boy was brought by his parents to a hospital in Spokane, Washington. The child was diagnosed as having cancer. Surgery was performed. Chemotherapy was begun. The child became extremely nauseated and vomited for days after each chemotherapy treatment. He could not eat regularly. He lost strength. He lost weight. His body's ability to ward off common infections, other life-threatening infections, significantly decreased. Chemotherapy's after-effects caused the child great suffering. They caused his watching

parents great suffering. Several standard, available anti-emetic agents were tried by the child's doctors. None of them succeeded in controlling his nausea or vomiting. Learning of the existence of research studies with THC or marijuana the parents asked the child's doctor to arrange for their son to be the subject of such a study so that he might have access to marijuana. The doctor refused, citing the volume of paperwork and record-keeping detail required in such programs and his lack of administrative personnel to handle it.

31. The child's mother read an article about marijuana smoking helping chemotherapy patients. She obtained some marijuana from friends. She baked cookies for her child with marijuana in them. She made tea for him with marijuana in it. When the child ate these cookies or drank this tea in connection with his chemotherapy, he did not vomit. His strength returned. He regained lost weight. His spirits revived. The parents told the doctors and nurses at the hospital of their giving marijuana to their child. None objected.

They all accepted smoking marijuana as effective in controlling chemotherapy induced nausea and vomiting. They were interested to see the results of the cookies.

32. Soon this child was riding a tricycle in the hallways of the Spokane hospital shortly after his chemotherapy treatments while other children there were still vomiting into pans, tied to intravenous bottles in an attempt to re-hydrate them, to replace the liquids they were vomiting up. Parents of some of the other patients asked the parents of this "lively" child how he seemed to tolerate his chemotherapy so well. They told of the marijuana use. Of those parents who began giving marijuana to their children, none ever reported back encountering any adverse side effects. In the vast majority of these cases, the other parents reported significant reduction in their children's vomiting and appetite stimulation as the result of marijuana. The staff, doctors and nurses at the hospital knew of this passing on of information about marijuana to other parents. They approved. They never told the first parents to hide their son's medicinal use of marijuana. They accepted the effectiveness of the cookies and the tea containing marijuana.

33. The first child's cancer went into remission. Then it returned and spread. Emotionally drained, the parents moved the family back to San Diego, California to be near their own parents. Their son was admitted to a hospital in San Diego. The parents informed the doctors, nurses and social workers there of their son's therapeutic use of marijuana. No one objected. The child's doctor in San Diego strongly

supported the parent's giving marijuana to him. Here in California, as in Spokane, other parents noticed the striking difference between their children after chemotherapy and the first child.

Other parents asked the parents of the first child about it, were told of the use of marijuana, tried it with their children, and saw dramatic improvement. They accepted its effectiveness. In the words of the mother of the first child: ". . . When your kid is riding a tricycle while his other hospital buddies are hooked up to IV needles, their heads hung over vomiting buckets, you don't need a federal agency to tell you marijuana is effective. The evidence is in front of you, so stark it cannot be ignored." [footnote 6]

34. There is at least one hospital in Tucson, Arizona where medicinal use of marijuana by chemotherapy patients is encouraged by the nursing staff and some physicians.

35. In addition to the physicians mentioned in the Findings above, mostly oncologists and other practitioners, the following doctors and health care professionals, representing several different areas of expertise, accept marijuana as medically useful in controlling or reducing emesis and testified to that effect in these proceedings:

a. George Goldstein, Ph.D., psychologist, Secretary of Health for the State of New Mexico from 1978 to 1983 and chief administrator in the implementation of the New Mexico program utilizing marijuana;

b. Dr. Daniel Danzak, psychiatrist and former head of the New Mexico program utilizing marijuana;

c. Dr. Tod Mikuriya, psychiatrist and editor of Marijuana: Medical Papers, a book presenting an historical perspective of marijuana's medical use;

d. Dr. Norman Zinberg, general psychiatrist and Professor of Psychiatry at Harvard Medical School since 1951;

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6 Affidavit of Janet Andrews, ACT rebuttal witness, par. 98.

e. Dr. John Morgan, psychopharmacologist, Board-certified in Internal Medicine, full Professor and Director of Pharmacology at the

City University of New York;

f. Dr. Phillip Jobe, neuropsychopharmacologist with a practice in Illinois and former Professor of Pharmacology and Psychiatry at the Louisiana State University School of Medicine in Shreveport, Louisiana, from 1974 to 1984;

g. Dr. Arthur Kaufman, formerly a general practitioner in Maryland, currently Vice-President of a private medical consulting group involved in the evaluation of the quality of care of all the U.S. military hospitals throughout the world, who has had extensive experience in drug abuse treatment and rehabilitation programs;

h. Dr. J. Thomas Ungerleider, a full Professor of Psychiatry at the University of California in Los Angeles with extensive experience in research on the medical use of drugs;

i. Dr. Andrew Weil, ethnopharmacologist, Associate Director of Social Perspectives in Medicine at the College of Medicine at the University of Arizona, with extensive research on medicinal plants; and

j. Dr. Lester Grinspoon, a practicing psychiatrist and Associate Professor at Harvard Medical School.

36. Certain law enforcement authorities have been outspoken in their acceptance of marijuana as an antiemetic agent. Robert T. Stephan, Attorney General of the State of Kansas, and himself a former cancer patient, said of chemotherapy in his affidavit in this record: "The treatment becomes a terror." His cancer is now in remission. He came to know a number of health care professionals whose medical judgment he respected. They had accepted marijuana

as having medical use in treatment. He was elected Vice President of the National Association of Attorneys General (NAAG) in 1983. He was instrumental in the adoption by that body in June 1983 of a resolution acknowledging the efficacy of marijuana for cancer and glaucoma patients. The resolution expressed the support of NAAG for legislation then pending in the Congress to make marijuana available on prescription to cancer and glaucoma patients. The resolution was adopted by an overwhelming margin. NAAG's President, the Attorney General of Montana, issued a statement that marijuana does have accepted medical uses and is improperly classified at present. The Chairman of NAAG's Criminal Law and Law Enforcement Committee, the Attorney General of Pennsylvania, issued a

statement emphasizing that the proposed rescheduling of marijuana would in no way affect or impede existing efforts by law enforcement authorities to crack down on illegal drug trafficking.

37. At least one court has accepted marijuana as having medical use in treatment for chemotherapy patients. On January 23, 1978 the Superior Court of Imperial County, California issued orders authorizing a cancer patient to possess and use marijuana for therapeutic purposes under the direction of a physician. Another order authorized and directed the Sheriff of the county to release marijuana from supplies on hand and deliver it to that patient in such form as to be usable in the form of cigarettes.

38. During the period 1978-1980 polls were taken to ascertain the degree of public acceptance of marijuana as effective in treating cancer and glaucoma patients. A poll in Nebraska brought slightly over 1,000 responses - 83% favored making marijuana available by prescription, 12% were opposed, 5% were undecided. A poll in Pennsylvania elicited 1,008 responses - 83.1% favored availability by prescription, 12.2% were opposed, 4.7% were undecided. These

two surveys were conducted by professional polling companies. The Detroit Free Press conducted a telephone poll in which 85.4% of those responding favored access to marijuana by prescription. In the State of Washington the State Medical Association conducted a poll in which 80% of the doctors belonging to the Association favored controlled availability of marijuana for medical purposes.

Discussion

From the foregoing uncontroverted facts it is clear beyond any question that many people find marijuana to have, in the words of the Act, an "accepted medical use in treatment in the United States" in effecting relief for cancer patients. Oncologists, physicians treating cancer patients, accept this. Other medical practitioners and researchers accept this. Medical faculty professors accept it. Nurses performing hands-on patient care accept it.

Patients accept it. As counsel for CCA perceptively pointed out at oral argument, acceptance by the patient is of vital importance. Doctors accept a therapeutic agent or process only if it "works" for the patient. If the patient does not accept, the doctor cannot administer the treatment. The patient's informed consent is vital. The doctor

ascertains the patient's acceptance by observing and listening to the patient. Acceptance by the doctor depends on what he sees in the patient and hears from the patient. Unquestionably, patients in large numbers have accepted marijuana as useful in treating their emesis. They have found that it "works". Doctors, evaluating their patients, can have no basis more sound than that for their own acceptance.

Of relevance, also, is the acceptance of marijuana by state attorneys-

general, officials whose primary concern is law enforcement. A large number of them have no fear that placing marijuana in Schedule II, thus making it available for legitimate therapy, will in any way impede existing efforts of law enforcement authorities to crack down on illegal drug trafficking.

The Act does not specify by whom a drug or substance must be "accepted [for] medical use in treatment" in order to meet the Act's "accepted" requirement for placement in Schedule II. Department of Justice witnesses told the Congress during hearings in 1970 preceding passage of the Act that "the medical Profession" would make this determination, that the matter would be "determined by the medical community." The Deputy Chief Counsel of BNDD, whose office had written the bill with this language in it, told the House subcommittee that "this basic determination . . . is not made by any part of the federal government. It is made by the medical community as to whether or not the drug has medical use or doesn't". [footnote 7]

No one would seriously contend that these Justice Department witnesses meant that the entire medical community would have to be in agreement on the usefulness of a drug or substance. Seldom, if ever, do all lawyers agree on a point of law. Seldom, if ever, do all doctors agree on a medical question. How many are required here? A majority of 51%? It would be unrealistic to attempt a plebiscite of all doctors in the country on such a question every time it arises, to obtain a majority vote.

In determining whether a medical procedure utilized by a doctor is actionable as malpractice the courts have adopted the rule what it is acceptable

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7 Drug Abuse Control Amendments - 1970: Hearings on H.R. 11701 and H.R. 13743 Before the Subcommittee on Public Health and Welfare of the House Committee on Interstate and Foreign Commerce, 91st

Congress, 2d Sess. 678, 696, 718 (1970) (Statement of John E. Ingersoll, Director, BNDD).

for a doctor to employ a method of treatment supported by a respectable minority of physicians.

In Hood v. Phillips, 537 S.W. 2d 291 (1976) the Texas Court of Civil Appeals was dealing with a claim of medical malpractice resulting from a surgical procedure claimed to have been unnecessary. The court quoted from an Arizona court decision holding that

> a method of treatment, as espoused and used by . . . a respectable minority of physicians in the United States, cannot be said to be an inappropriate method of treatment or to be malpractice as a matter of law even though it has not been accepted as a proper method of treatment by the medical profession generally.

Ibid. at 294. Noting that the Federal District court in the Arizona case found a "respectable minority" composed of sixty-five physicians throughout the United States, the Texas court adopted as "the better rule" to apply in its case, that

> a physician is not guilty of malpractice where the method of treatment used is supported by a respectable minority of physicians.

Ibid.

In Chumbler v. McClure, 505 F.2d 489 (6th Cir. 1974) the Federal courts were dealing with a medical malpractice case under their diversity jurisdiction, applying Tennessee law. The Court of Appeals said:

> . . . The most favorable interpretation that may be placed on the testimony adduced at trial below is that there is a division of opinion in the medical profession regarding the use of Premarin in the Treatment of cerebral vascular insufficiency, and that Dr. McClure was alone among neurosurgeons in Nashville in using such therapy. The test for malpractice and for community standards is not to be determined solely by a plebiscite. Where two or more schools of thought exist among competent members of the medical profession concerning proper medical treatment for a given

ailment, each of which is supported by responsible

> medical authority, it is not malpractice to be among the minority in a given city who follow: one of the accepted schools.

505 F.2d at 492 (Emphasis added). See, also, Leech v. Bralliar, 275 F.Supp. 897 (D.Ariz., 1967).

How do we ascertain whether there exists a school of thought supported by responsible medical authority, and thus "accepted"? We listen to the physicians.

> The court and jury must have a standard measure which they are to use in measuring the acts of a doctor to determine whether he exercised a reasonable degree of care and skill; they are not permitted to set up and use any arbitrary or artificial standard of measurement that the jury may wish to apply. The proper standard of measurement is to be established by testimony of physicians, for it is a medical question.

Hayes v. Brown, 133 S.E. 2d. 102 (Ga., 1963) at 105.

As noted above, there is no question but that this record shows a great many physicians, and others, to have "accepted" marijuana as having a medical use in the treatment of cancer patients' emesis. True, all physicians have not "accepted" it. But to require universal, 100% acceptance would be unreasonable. Acceptance by "a respectable minority" of physicians is all that can reasonably be required. The record here establishes conclusively that at least "a respectable minority" of physicians has "accepted" marijuana as having a "medical use in treatment in the United states." That others may not makes no difference.

The administrative law judge recommended this same approach for determining whether a drug has an "accepted medical use in treatment" in The Matter Of MDMA Scheduling, Docket No. 84-48. The Administrator, in his first final rule in that proceeding, issued on October 8, 1986 [footnote 8], declined to adopt this approach. He

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8 51 Fed. Reg. 36552 (1986).

ruled, instead, that DEA's decision on whether or not a drug or other substance had an accepted medical use in treatment in the United States would be determined simply by ascertaining whether or not "the drug or other substance is lawfully marketed in the United States pursuant to the Federal Food, Drug and Cosmetic Act of 1938 . . . ." [footnote 9]

The United States Court of A eals for the First Circuit held that the Administrator erred in so ruling. [footnote 10] That court vacated the final order of October 8, 1986 and remanded the matter of MDMA's scheduling for further consideration. The court directed that, on remand, the Administrator would not be permitted to treat the absence of interstate marketing approval by FDA as conclusive evidence on the question of accepted medical use under the Act.

In his third final rule [footnote 11] of the matter of the scheduling of MDMA the Administrator made a series of findings of fact as to MDMA, the drug there under consideration, with respect to the evidence in that record. On those findings he based his last final rule in the case. [footnote 12]

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9 Ibid., at 36558.

10 Grinspoon v. Drug Enforcement Administration, 828 F.2d 881 (1st. Cir., 1987).

11 53 Fed. Reg. 5156 (1988). A second final rule had been issued on January 20, 1988. It merely removed MDMA from Schedule I pursuant to the mandate of the Court of Appeals which had voided the first final rule placing it there. Subsequently the third final rule was issued, without any further hearings, again placing MDMA in Schedule I. There was no further appeal.

12 In neither the first nor the third final rule in the MDMA case does the Administrator take any cognizance of the statements to the Congressional committee by predecessor Agency officials that the determination as to "accepted medical use in treatment" is to be made by the medical community and not by any part of the federal government. See page 27, above. It is curious that the administrator makes no effort whatever to show how the BNDD representatives were mistaken or to explain why he now has abandoned their interpretation. They wrote that language into the original bill.

That third final rule dealing with MDMA is dealing with a synthetic, "simple", "single-action" drug. What might be appropriate criteria for a "simple" drug like MDMA may not be appropriate for a "complex" substance with a number of active components. The criteria applied to MDMA, a synthetic drug, are not appropriate for application to marijuana, which is a natural plant substance.

The First Circuit Court of Appeals in the MDMA case told the Administrator that he should not treat the absence of FDA interstate marketing approval as conclusive evidence of lack of currently accepted medical use. The court did not forbid the Administrator from considering the absence of FDA approval as a factor when determining the existence of accepted medical use. Yet on remand, in his third final order, the Administrator adopted by reference 18 of the numbered findings he had made in the first final order. Each of these findings had to do with requirements imposed by FDA for approval of a new drug application (NDA) or of an investigational new drug exemption (IND). These requirements deal with data resulting from controlled studies and scientifically conducted investigations and test.

Among those findings incorporated into the third final MDMA order from the first, and relied on by the Administrator, was the determination and recommendation of the FDA that the drug there in question was not "accepted". In relying on the FDA's action the Administrator apparently overlooked the fact that the FDA clearly stated that it was interpreting "accepted medical use" in the Act as being equivalent to receiving FDA approval for lawful marketing under the FDCA. Thus the Administrator accepted as a basis for his MDMA third final rule the FDA recommendation which was based upon a statutory interpretation which the Court

of Appeals had condemned.

The Administrator in that third final rule made a series of further findings. Again, the central concern in these findings was the content of test results and the sufficiency or adequacy of studies and scientific reports. A careful reading of the criteria considered in the MDMA third final order reveals that the Administrator was really considering the question: Should the drug be accepted for medical use?; rather than the question: Has the drug been accepted for medical use? By considering little else but scientific test results and reports the Administrator was making a determination as to whether or not, in his opinion, MDMA ought to be accepted for medical use in treatment.

The Agency's arguments in the present case are to the same effect.

In a word, they address the wrong question. It is not for this Agency to tell doctors whether they should or should not accept a drug or substance for medical use. The statute directs the Administrator merely to ascertain whether, in fact, doctors have done so.

The MDMA third final order mistakenly looks to FDA criteria for guidance in choosing criteria for DEA to apply. Under the Food, Drug and Cosmetic Act the FDA is deciding - properly, under that statute - whether a new drug should be introduced into interstate commerce. Thus it is appropriate for the FDA to rely heavily on test results and scientific inquiry to ascertain whether a drug is effective and whether it is safe. The FDA must look at a drug and pass judgment on its intrinsic qualities. The DEA, on the other hand, is charged by 21 U.S.C. § 812(b)(1)(B) and (2)(B) with ascertaining what it is that other people have done with respect to a drug or substance: "Have they accepted it?," not "Should they accept it?"

In the MDMA third final order DEA is actually making the decision that doctors have to make, rather than trying to ascertain the decision which doctors have made. Consciously or not, the Agency is undertaking to tell doctors what they should or should not accept. In so doing the Agency is acting beyond the authority granted in the Act.

It is entirely proper for the Administrator to consider the pharmacology of a drug and scientific test results in connection with determining abuse potential. But abuse potential is not in issue in this marijuana proceeding.

There is another reason why DEA should not be guided by FDA criteria in ascertaining whether or not marijuana has an accepted medical use in treatment. These criteria are applied by FDA pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act (FDCA), as amended. [footnote 13] When the FDA is making an inquiry pursuant to that legislation it is looking at a synthetically formed new drug. The marijuana plant is anything but a new drug. Uncontroverted evidence in this record indicates that marijuana was being used therapeutically by mankind 2000 years before the Birth of Christ. [footnote 14]

Uncontroverted evidence further establishes that in this country today "new drugs" are developed by pharmaceutical companies possessing resources sufficient to bear the enormous expense of testing a new drug, obtaining FDA approval of its efficacy and safety, and marketing it successfully. No company undertakes the investment required unless it has a patent on the drug, so it can recoup its development costs and make

a profit. At oral argument Government counsel conceded that "the FDA system is constructed for pharmaceutical companies. I won't

13 21 U.S.C. § 355.

14 Alice M. O'Leary, direct, par. 9.

deny that." [footnote 15]

Since the substance being considered in this case is a natural plant rather than a synthetic drug, it is unreasonable to make FDA-type criteria determinative of the issue in this case, particularly so when such criteria are irrelevant to the question posed by the act: does the substance have an accepted medical use in treatment?

Finally, the Agency in this proceeding relies in part on the FDA's recommendation that the Administrator retain marijuana in Schedule I. But, as in the MDMA case, that recommendation is based upon FDA's equating "accepted medical use" under the Act with being approved for marketing by FDA under the Food, Drug and Cosmetic Act, the interpretation condemned by the First Circuit in the MDMA case. See Attachment A, p.24, to exhibit G-1 and exhibit G-2.

The overwhelming preponderance of the evidence in this record establishes that marijuana has a currently accepted medical use in treatment in the United States for nausea and vomiting resulting from chemotherapy treatments in some cancer patients. To conclude otherwise, on this record, would be unreasonable, arbitrary and capricious.

15 Tr. XV-37.

Click here for Part 3

VI.

ACCEPTED MEDICAL USE IN TREATMENT
- GLAUCOMA

Findings of Fact

The preponderance of the evidence establishes the following facts with respect to the accepted medical use of marijuana in the treatment of glaucoma.

1. Glaucoma is a disease of the eye characterized by the excessive accumulation of fluid causing increased intraocular pressure, distorted vision and, ultimately, blindness. In its early stages this pressure can sometimes be relieved by the administration of drugs. When such medical treatment fails adequately to reduce the intraocular pressure (IOP), surgery is generally resorted to. Although useful in many cases, there is a high incidence of failure with some types of surgery. Further, serious complications can occur as a result of invasive surgery. Newer, non-invasive procedures such as laser trabeculoplasty are thought by some to offer much greater efficacy with fewer complications. Unless the IOP is relieved and brought to a satisfactory level by one means or another, the patient will go blind.

2. Two highly qualified and experienced ophthalmologists in the United States have accepted marijuana as having a medical use in treatment for glaucoma. They are John C. Merritt, M.D. and Richard D. North, M.D. Each of them is both a clinician, treating patients, and a researcher. Dr. Merritt is also a professor of ophthalmology. Dr. North has served as a medical officer in ophthalmology for the Department of Health, Education and Welfare and has worked with the Public Health Service and FDA.

3. Dr. Merritt's experience with glaucoma patients using marijuana medicinally includes one Robert Randall and, insofar as the evidence here establishes per petitioners' briefs, an unspecified number of other patients, something in excess of 40.

4. Dr. North has treated only one glaucoma patient using marijuana medicinally - the same Robert Randall mentioned immediately above. Dr. North had monitored Mr. Randall's medicinal use of marijuana for nine years as of May 1987

5. Dr. Merritt has accepted marijuana as having an important place in the treatment of "End Stage" glaucoma. "End Stage" glaucoma, essentially, defines a patient who has already lost substantial amounts of vision; available glaucoma control drugs are no longer able adequately to reduce the intraocular pressure (IOP) to prevent further, progressive sight loss; the patient, lacking additional IOP reductions, will go blind.

6. Robert S. Hepler, M.D., is a highly qualified and

experienced ophthalmologist. He has done research with respect to the effect of smoking marijuana on glaucoma. In December 1975 he prescribed marijuana for the same Robert Randall mentioned above as a research subject. Dr. Hepler found that large dosages of smoked marijuana effectively reduced Robert Randall's IOP into the safe range over an entire test day. He concluded that the only known alternative to preserve Randall's sight which would avoid the significant risks of surgery is to include marijuana as part of Randall's prescribed medical regimen. He further concluded in 1977 that, if marijuana could have been legally prescribed, he would have prescribed it for Randall as part of Randall's regular glaucoma maintenance program had he been Randall's personal physician.

Nonetheless, in 1987 Dr. Hepler was of the opinion that marijuana did not have a currently accepted medical use in the United States for the treatment of glaucoma.

7. Four glaucoma patients testified in these proceedings. Each has found marijuana to be of help in controlling IOP.

8. In 1984 the treatment of glaucoma with Cannabis was the subject of an Ophthalmology Grand Rounds at the University of California, San Francisco. A questionnaire was distributed which queried the ophthalmologists on cannabis therapy for glaucoma patients refractory to standard treatment. Many of them have glaucoma patients who have asked about marijuana. Most of the responding ophthalmologists believed that THC capsules or smoked marijuana need to be available for patients who have not benefited significantly from standard treatment.

9. In about 1978 an unspecified number of persons in the public health service sector in New Mexico, including some physicians, accepted marijuana as having medical use in treating glaucoma.

10. A majority of an unspecified number of ophthalmologists known to Arthur Kaufman, M.D., who was formerly in general practice but now is employed as a medical program administrator, accept marijuana as having medical use in treatment of glaucoma.

11. In addition to the physicians identified and referred to in the findings above, the testimony of patients in this record establishes that no more than three or four other physicians consider marijuana to be medically useful in the treatment of glaucoma in the United States. One of those Physicians actually wrote a prescription for marijuana for a patient, which, of course, she was unable to have filled.

12. There are test results showing that smoking marijuana has reduced the IOP in some glaucoma patients. There is continuing research underway in the United States as to the therapeutic effect of marijuana on glaucoma.

Discussion

Petitioners' briefs fail to show that the preponderance of the evidence in the record with respect to marijuana and glaucoma establishes that a respectable minority of physicians accepts marijuana as being useful in the treatment of glaucoma in the United States.

This conclusion is not to be taken in any way as criticism of the opinions of the ophthalmologists who testified that they accept marijuana for this purpose. The failure lies with petitioners. In their briefs they do not point out hard, specific evidence in this record sufficient to establish that a respectable minority of physicians has accepted their position.

There is a great volume of evidence here, and much discussion in the briefs, about the protracted case of Robert Randall. But when all is said and done, his experience presents but one case. The record contains sworn testimony of three ophthalmologists who have treated Mr. Randall. One of them tells us of a relatively small number of other glaucoma patients whom he has treated with marijuana and whom he knows to have responded favorably. Another of these three doctors has successfully treated only Randall with marijuana. The third testifies, despite his successful experience in treating Randall, that marijuana does not have an accepted use in such treatment.

In addition to Robert Randall, Petitioners point to the testimony of three other glaucoma patients. Their case histories are impressive, but they contribute

little to the carrying of Petitioner's burden of showing that marijuana is accepted for medical treatment of glaucoma by a respectable minority of physicians. See pages 26-29, above.

Petitioners have in evidence copies of a number of newspaper clippings reporting statements by persons claiming that marijuana has helped their glaucoma. The administrative law judge is unable to give

significant weight to this evidence. Had these persons testified so as to have been subject to cross-examination, a different situation would be presented. But these newspaper reports of extra-judicial statements, neither tested by informed inquiry nor supported by a doctor's opinion, are not entitled to much weight. They are of little, if any, materiality.

Beyond the evidence referred to above there is a little other "hard" evidence, pointed out by petitioners, of Physicians accepting marijuana for treatment of glaucoma. Such evidence as that concerning a survey of a group of San Francisco ophthalmologists is ambiguous, at best. The relevant document establishes merely that most of the doctors on the grand round, who responded to an inquiry, believed that the THC capsules or marijuana ought to be available.

In sum, the evidence here tending to show that marijuana is accepted for treatment of glaucoma falls far, far short of quantum of evidence tending to show that marijuana is accepted for treatment of emesis in cancer patients. The preponderance of the evidence here, identified by petitioners in their briefs, does not establish that a respectable minority of physicians has accepted marijuana for glaucoma treatment.

VII.

ACCEPTED MEDICAL USE IN TREATMENT - MULTIPLE SCLEROSIS, SPASTICITY AND HYPERPARATHYROIDISM

Findings Of Fact

The preponderance of the evidence clearly establishes the following facts with respect to marijuana's use in connection with multiple sclerosis, spasticity and hyperparathyroidism.

1. Multiple sclerosis is the major cause of neurological disability among young and middle-aged adults in the United States today. It is a life-long disease. It can be extremely debilitating to some of its victims but it does not shorten the life span of most of them. Its cause is yet to be determined. It attacks the myelin sheath, the coating or insulation surrounding the message-carrying nerve fibers in the brain and spinal cord. Once the myelin sheath is destroyed, it is replaced by plaques of hardened tissue known as sclerosis. During the initial stages of the disease nerve impulses are transmitted with only minor

interruptions. As the disease progresses, the plaques may completely obstruct the impulses along certain nerve systems. These obstructions produce malfunctions. The effects are sporadic in most individuals and the effects often occur episodically, triggered either by malfunction of the nerve impulses or by external factors.

2. Over time many patients develop spasticity, the involuntary and abnormal contraction of muscle or muscle fibers. (Spasticity can also result from serious injuries to the spinal cord, not related to multiple sclerosis.)

3. The symptoms of multiple sclerosis vary according to the area of

the nervous system which is affected and according to the severity of the disease. The symptoms can include one or more of the following: weakness, tingling, numbness, impaired sensation, lack of coordination, disturbances in equilibrium, double vision, loss of vision, involuntary rapid movement of the eyes (nystagmus), slurred speech, tremors, stiffness, spasticity, weakness of limbs, sexual dysfunction, paralysis, and impaired bladder and bowel functions.

4. Each person afflicted by multiple sclerosis is affected differently. In some persons, the symptoms of the disease are barely detectable, even over long periods of time. In these cases, the persons can live their lives as if they did not suffer from the disease. In others, more of the symptoms are present and acute, thereby limiting their physical capabilities. Moreover, others may experience sporadic, but acute, symptoms.

5. At this time, there is no known prevention or cure for multiple sclerosis. Instead, there are only treatments for the symptoms of the disease. There are very few drugs specifically designed to treat spasticity. These drugs often cause very serious side effects. At the present time two drugs are approved by FDA as "safe" and "effective" for the specific indication of spasticity. These drugs are Dantrium and Lioresal baclofen.

6. Unfortunately, neither Dantrium nor Lioresal is a very effective spasm control drug. Their marginal medical utility, high toxicity and potential for serious adverse effects make these drugs difficult to use in spasticity therapy.

7. As a result, many physicians routinely prescribe

tranquilizers, muscle relaxants, mood elevators and sedatives such as Valium to patients experiencing spasticity. While these drugs do not directly reduce spasticity

they may weaken the patient's muscle tone, thus making the spasms less noticeable. Alternatively, they may induce sleep or so tranquilize the patient that normal mental and physical functions are impossible.

8. A healthy, athletic young woman named Valerie Cover was stricken with multiple sclerosis while in her early twenties. She consulted several medical specialists and followed all the customary regimens and prescribed methods for coping with this debilitating disease over a period of several years. None of these proved availing. Two years after first experiencing the symptoms of multiple sclerosis her active, productive life - as an athlete, Navy officer's wife and mother - was effectively over. The Social Security Administration declared her totally disabled. To move about her home she had to sit on a skateboard and push herself around. She spent most of her time in bed or sitting in a wheelchair.

9. An occasional marijuana smoker in her teens, before her marriage, she had not smoked it for five years as of February 1986. Then a neighbor suggested that marijuana just might help Mrs. Cover's multiple sclerosis, having read that it had helped cancer patient's control their emesis. Mrs. Cover acceded to the suggestion.

10. Just before smoking the marijuana cigarette produced by her neighbor, Mrs. Cover had been throwing up and suffering from spasms. Within five minutes of smoking part of the marijuana cigarette she stopped vomiting, no longer felt nauseous and noticed that the intensity of her spasms was significantly reduced. She stood up unaided.

11. Mrs. Cover began smoking marijuana whenever she felt nauseated. When she did so it controlled her vomiting, stopped the nausea and increased her

appetite. It helped ease and control her spasticity. Her limbs were much easier to control. After three months of smoking marijuana she could walk unassisted, had regained all of her lost weight, her seizures became almost nonexistent. She could again care for her children. She could drive an automobile again. She regained the ability to lead a normal life.

12. Concerned that her use of this illegal substance might jeopardize the career of her Navy officer husband, Mrs. Cover stopped smoking marijuana several times. Each time she did so, after about a month, she had retrogressed to the point that her multiple sclerosis again had her confined to bed and wheelchair or skateboard. As of the Spring of 1987 Mrs. Cover had resumed smoking marijuana regularly on an "as needed" basis. Her multiple sclerosis symptoms are under excellent control. She has obtained a full-time job. She still needs a wheelchair on rare occasions, but generally has full use of her limbs and can walk around with relative ease.

13. Mrs. Cover's doctor has accepted the effectiveness of marijuana in her case. He questioned her closely about her use of it, telling her that it is the most effective drug known in reducing vomiting. Mrs. Cover and her doctor are now in the process of filing an Investigational New Drug (IND) application with FDA so that she can legally obtain the marijuana she needs to lead a reasonably normal life.

14. Martha Hirsch is a young woman in her mid-thirties. She first exhibited symptoms of multiple sclerosis at age 19 and it was diagnosed at that time. Her condition has grown progressively worse. She has been under the care of physicians and hospitalized for treatment. Many drugs have been prescribed for her by her doctors. At one point in 1983 she listed the drugs that had been

prescribed for her. There were 17 on the list. None of them has given her the relief from her multiple sclerosis symptoms that marijuana has.

15. During the early stages in the development of her illness Ms. Hirsch found that smoking marijuana improved the quality of her life, keeping her spasms under control. Her balance improved. She seldom needed to use her cane for support. Her condition lately has deteriorated. As of May 1987 she was experiencing severe, painful spasms. She had an indwelling catheter in her bladder. She had lost her locomotive abilities and was wheelchair bound. She could seldom find marijuana on the illegal market and, when she did, she often could not afford to purchase it. When she did obtain some, however, and smoked it, her entire body seemed to relax, her spasms decreased or disappeared, she slept better and her dizzy spells vanished. The relaxation of her leg muscles after smoking marijuana has been confirmed by her personal care attendant's examination of them.

16. The personal care attendant has told Ms. Hirsch that she,

the attendant, treats a number of patients who smoke marijuana for relief of multiple sclerosis symptoms. In about 1980 another patient told Ms. Hirsch that he knew many patients who smoke marijuana to relieve their spasms. Through him she met other patients and found that marijuana was commonly used by many multiple sclerosis patients. Most of these persons had told their doctors about their doing so. None of those doctors advised against the practice and some encouraged it.

17. Among the drugs prescribed by doctors for Ms. Hirsch was ACTH. This failed to give her any therapeutic benefit or to control her spasticity. It did produce a number of adverse effects, including severe nausea and vomiting which, in turn, were partly controlled by rectally administered anti-emetic

drugs.

18. Another drug prescribed for her was Lioresal, intended to reduce her spasms. It was not very effective in doing. But it did cause Ms. Hirsch to have hallucinations. On two occasions, while using this drug, Ms. Hirsch "saw" a large fire in her bedroom and called for help. There was no fire. She stopped using that drug. Ms. Hirsch has experienced no adverse reactions with marijuana.

19. Ms. Hirsch's doctor has accepted marijuana as beneficial for her. He agreed to write her a prescription for it, if that would help her obtain it. She has asked him if he would file an IND application with the FDA for her. He replied that the paperwork was "overwhelming". He indicated willingness to put the paper work together.

20. When Greg Paufler was in his early twenties, employed by Prudential Insurance Company, he began to experience the first symptoms of multiple sclerosis. His condition worsened as the disease intensified. He had to be hospitalized. He lost the ability to walk, to stand. Diagnosed as having multiple sclerosis, a doctor prescribed ACTH for him, an intensive form of steroid therapy. He lost all control over his limbs and experienced severe, painful spasms. His arms and legs became numb.

21. ACTH had no beneficial effects. The doctor continued to prescribe it many months. ACTH made Paufler ravenously hungry and he began gaining a great deal of weight. ACTH caused fluid retention and Paufler became bloated, rapidly gaining weight. His doctor thought Paufler should continue this steroid therapy, even though it caused the adverse effects mentioned plus the possibility of sudden heart attack or

Physical, Mental, and Moral Effects of Marijuana: The Indian Hemp Drugs Commission Report

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The Indian Hemp Drugs Commission Report (1894), comprising some seven volumes and 3,281 pages, is by far the most complete and systematic study of marijuana undertaken to date. Because of the rarity and, perhaps, the formidable size of this document, the wealth of information contained in it has not found its way into contemporary writings on this subject. This is indeed unfortunate, as many of the issues concerning marijuana being argued in the United States today were dealt with in the Indian Hemp Drugs Commission Report.

It is both surprising and gratifying to note the timeless and lucid quality of the writings of these British colonial bureaucrats. It would be fortunate if studies undertaken by contemporary commissions, task force committees, and study groups could measure up to the standards of thoroughness and general objectivity embodied in this report. In the current context of violently polarized attitudes toward marijuana, the prospect of a study of similar stature is bleak.

The scope of this paper is necessarily limited to the issues of physical, mental, and moral effects of hemp drugs as discussed in the report, although the topics of cultivation, processing, and administrative control schemes make up significant portions of the work itself.

History of British Involvement

The British government in India had substantial knowledge of intoxicants other than alcohol because of active involvement in regulation, taxation, and actual trafficking in these substances for over a hundred years prior to the Hemp Drugs Commission investigation and report.

In 1790 duties on alcohol and other intoxicant drugs were first levied by the British on landlords in India. The regulation of cannabis preparations was further specified in 1793 in Regulation XXXIV of that year. "No person shall manufacture or vend any such drugs (bhang,2 ganja,3 charas,4 and other intoxicating drugs) without a license from the collector of the zillah5" (3:16).

This system of regulations was instituted "with a view to check immoderate consumption, and at the same time to augment the public revenue" (3:16).

In 1800 in a further modification of regulation, the manufacture and sale of charas was prohibited as "being of a most noxious quality" (3:16), while daily rates of duty were declared as the basis for taxing procedures. Curiously, in 1824 the restriction on charas was rescinded "as this drug was found on examination to be not more prejudicial to health than ganja or other intoxicating drugs" (3:16).

In 1849 limits on retail sale of cannabis drugs were fixed "for better securing the abkari6 revenue of Calcutta," and later extended to the whole of Bengal (3:16). Four years later the daily tax method was abandoned and a fee charged on a per weight basis, and in 1860 an additional set of dealers fees' imposed (3:16).

It should be noted, however, that the system of the state of Bengal was only one of several schemes among the many provinces. Variations on this approach existed in the other states, a function of the differing local administrations, reflecting the degree of administrative and fiscal controls exerted by the Imperial government.

There had apparently been controversies as to the possible noxious effects of cannabis drugs at least from the time of the inception of British controls on these products, unless we assume that the initial stated reasons for regulation were merely cynical rationalizations for obtaining additional sources of revenue. Within a country of several hundred millions of inhabitants, divided into hundreds of regions, and with only rudimentary "homogenizing" forces of effective transportation and mass media, it is perhaps reasonable to infer that wide variations in opinions and beliefs would be encountered.

1 *Report of the Indian Hemp Drugs Commission, 1893-94*. Simla, India: Government Central Printing House, 1894, 7 vols. All references in this paper are to volumes of the Report.

Received for publication December 1967

2 Leaves and flowers of wild growing or inferior cultivated cannabis plants.

3 Flowering tops of the cannabis plant.

4 Resin from the mature cannabis plant.

5 A county-sized district or administrative division.

6 Manufacture or sale of intoxicating liquors or drugs: hence, an excise or internal revenue tax on such manufacture or sale (Ankara: A wine seller; distiller. Also, one whose trade is subject to abkari tax).

FORMATION OF THE COMMISSION

On 2 March 1893 (1:1,n) a question was raised in the British House of Commons concerning the effects of the production and consumption of hemp drugs in the province of Bengal, India. In response, the Government of India convened a seven-member commission to look into these questions on 3 July 1893 (1:1). Upon the suggestion of Lord Kimberley the scope of the investigation was expanded to include all of India.

PROCEDURES

The Commission actually met for the first time in Calcutta on 3 August 1893 (1:4). Between this date and 6 August of the following year, when the study was finished (1:361), the Commission received evidence from

1,193 witnesses (1:12). Field trips were made to thirty cities in eight provinces and Burma from the end of October 1893 through the latter part of April 1894 (1:9-10). Eighty-six meetings for examination of witnesses transpired during the inquiry. Actual participation of the members of the Commission was duly noted and reported - a custom that it might be worthwhile to revive.

[redacted] statement on the previous page shows the attendance of the members of the Commission during the period occupied in inquiry (3rd August 1893 to 25th April 1894).

Witnesses whose evidence was received by the Commission were divided into three categories:

(1) Official witnesses able to give information regarding hemp drugs, based on their official and local experience.

(2) Non-official witnesses of all ranks able to give information regarding the drugs generally or in connection with certain classes of the people.

(3) Other persons or associations having facts or holding opinions which they desired to communicate to the Commission (1:11).

Categories and numbers of the witnesses were (1:12):

Civil Officers 197

Medical Officers 214

Private Practitioners (European methods) 34

[redacted]vate Practitioners (Native methods) 87

Cultivators 144

Professional Men 55

Missionaries 34

Associations 24

Persons engaged in Trade 75

Others 59

Total 1,193

To facilitate collection of information, seventy questions framed by the Commission were given to the witnesses. The written answers to these questions constituted the bulk of the evidence before the Commission (1:13). Where appropriate, witnesses were examined orally for further clarification or explanation. In addition, witnesses who had not submitted written statements were examined orally. It was duly noted in the record which forms of testimony had been provided by the individual witnesses. The following were the questions dealing with effects of hemp drugs with regard to adverse physical [redacted]nsequences, insanity, and the causation of crime (4:iii):

45. (a) Does the habitual moderate use of any of these drugs produce any noxious effects - physical, mental, or moral?

(b) Does it impair the constitution in any way?

(c) Does it injure the digestion or cause loss of appetite?

Does it cause dysentery, bronchitis, or asthma?

(e) Does it impair the moral sense or induce laziness or habits of immortality or debauchery?

(f) Does it deaden the intellect or produce insanity?

If it produces insanity, then of what type, and is it temporary or permanent?

If temporary, may the symptoms be re-induced by use of the drug after liberation from restraint?

Are there any typical symptoms?

Do insanes, who have no recorded ganja history, confess to the use of the drug?

(g) In such cases of the alleged connection between insanity and the use of hemp as are known to you, are you of opinion that the use of the drug by persons suffering from mental anxiety or brain disease to obtain relief his been sufficiently considered in explaining that connection?

And do you think there is any evidence to indicate that insanity may often tend to indulgence in the use of hemp drugs by a person who is deficient in self-control through weakened intellect?

Give an account under each of these points of any cased with which you are acquainted.

. Discuss the same questions in regard to the habitual excessive use of any of these drugs.

51. (a) Are any large proportion of bad characters habitual moderate consumers of any of these drugs?

(b) What connection, if any, has the moderate use with crime in general or with crime of any special character?

52. Discuss the same question in regard to the excessive use of any of these drugs.

53. Does excessive indulgence in any of these drugs incite to unpremeditated crime, violent or otherwise? Do you know of any case in which it has led to temporary homicidal frenzy?

1. Are these drugs used by criminals to fortify themselves to commit a premeditated act of violence or other crime?

Physical Effects of Chronic Cannabis Use

The Commission sought to evaluate alleged connections of hemp drug use with disorders other than mental. Popular opinion held that the use of hemp drugs led to the physical disorders of dysentery, bronchitis, and asthma:

regard to these definite physical results, the only evidence to which much weight can be attached is the evidence of the medical witnesses. From their training and opportunities of observation they are the only witnesses qualified to give reliable evidence. It is proposed to examine this medical evidence in detail

(1:205).

The Commission reviewed and discussed medical evidence given by 335 physicians7 throughout India from Bengal, Assam, North-Western Provinces, Punjab, Central Provinces, Madras, Bombay, Sind, Burma, and Behar. The testimony from the array of medical witnesses from Bengal illustrates the confusion and the lack of knowledge among the members of our profession:

In Bengal eight commissioned medical officers were examined on the effect of the ...oderate use of the drugs. Surgeon-Lieutenant-Colonel Russell (witness No. 105), 20 years in civil employ in Bengal and Assam, a witness whose evidence has frequently been quoted by the Commission, stated that the use of the drug does not cause bronchitis, dysentery, or asthma, and that scarcely any other noxious effects are induced. Surgeon-Lieutenant-Cclonel Russiel Lall Dutt (witness No. 107) an officer of over 20 years' experience, stated "Very moderate smoking of Ganja or charas or moderate drinking of siddhi in infusion do not produce any appreciable effects. . . but these moderate cases are seldom long-lived. There is in them a slow and insidious undermining process going on in their digestive, respiratory, and nervous system, which predispose them to acute diseases and cut their lives short." Surgeon-Lieutenant-Colonel Price (witness No. 108), of 21 years' service, who had frequently come across consumers of hemp drugs, was unable to answer the question regarding effects. Surgeon-Captain Prain (witness No. 113) stated: "I do not believe that the habitual moderate use of any of these drugs produces any noxious effects - physical, mental, or moral. I think that perhaps the use of bhang does injure the digestion and impair appetite even when used moderately, but I am convinced that it neither causes dysentery, bronchitis, or asthma." Surgeon-Major Cobb (witness No. 110) stated that the drugs did not cause asthma, bronchitis, or dysentery; and in cross-examination he stated: "I have no experience that the excessive use of the drug produces dysentery and bowel complaints." Surgeon-Lieutenant-Colonel Flood Murray (witness No. 102),

five years in military service and nineteen years in civil employ, quoted the opinion of a pandit8 whom he consulted regarding the ill effects of the drugs. In cross-examination he stated: "The general statement as contained in my written answer is a statement made to me by this hakim9 and others to whom I applied for information. *My own experience in no way corroborates it.*" Surgeon-Lieutenant-Colonel Bovill (witness No. 109), of 21 years' service, stated that the habitual moderate use of bhang does not produce any ill effects, and in many cases that of ganja is equally harmless. He added; "I know of no case where it has caused bronchitis, dysentery, or asthma, but I have noted hoarseness of the voice probably due to some laryngeal irritation among ganja smokers." Surgeon-Lieutenant-Colonel Crombie (witness No. 104), of over 20 years' service, is not aware of any ill effects being produced by the moderate use of the drugs; but he added: "If any were produced, the use would no longer be moderate, but excessive." In cross-examination Dr. Crombie stated: "I have had no experience of any diseases attributable to ganja. My experience has been chiefly in Eastern Bengal, where ganja is largely consumed."

Twenty-three assistant surgeons were examined. Assistant Surgeon Devendranath Roy (witness No. 123), of over 20 years' service, and who has had service in Rajputana, the North-Western Provinces, Behar, and Bengal, where hemp drugs are used by a large portion of the people, is of opinion that those who smoke ganja not more than twice or thrice a day do not suffer in general health; bhang does not impair the digestion, whereas ganja does. "Those of my patients," he remarks "who admitted having been habitual ganja smokers suffered from dysentery or diarrhoea, but they have been exposed to conditions which produce these ailments. Hence I do not draw any conclusion as to ganja being a primary cause of those diseases." Assistant Surgeon Preonath Bose (witness No. 122), Teacher of Materia Medica and Pharmacy in the Dacca Medical School, clearly has no personal knowledge of the effects, as he remarked: "Evidence on these points is conflicting. Some of the consumers maintain, others deny, that evil effects are produced." Another teacher at the same school (witness No. 121) stated: "Evidence on these points is conflicting. The general consensus of opinion is that the habitual moderate use of bhang and ganja does not impair the constitution." Assistant Surgeon Soorjee Narain Singh, of 28 years' service, now Teacher of Materia Medica,

Patna Medical School (witness No. 125), stated that "habitual moderate consumers of bhang, ganja or charas do not apparently suffer from any injurious effects." Assistant Surgeon Narendra Nath Gupta (witness No. 120), as Deputy Superintendent of Vaccination and as Deputy Sanitary Commissioner and as Civil Medical Officer has had considerable opportunities for noting the effects of the drugs. His opinion is that the [illegible]erate use of ganja and bhang does not produce any noxious effects. Durga Dass Lahiri, L.M.S. (witness [illegible] 132), a private medical practitioner, said: "I have not seen any evil results mentioned when taken moderately, but it is very difficult to keep to moderation." Assistant Surgeon Taraprosanna Roy (witness No. 116) is Chemical Examiner to the Government of Bengal. He stated that the habitual moderate use of the three drugs is not known to produce any noxious effects. Assistant Surgeon Bosonto Kumar Sen (witness No. 119) has had service in ganja producing districts. He stated that the use of ganja and bhang products noxious effects, and "generally produce dysentery, asthma, and bronchitis." The cross examination of this witness is of interest. "I have seen more than one person, about half a dozen, in my village. . . suffering from dysentery, bronchitis, and asthma who were also ganja smokers. *They were all excessive smokers.* These effects do not follow the moderate, but the excessive, use. It is a mistake to have put them under the moderate use. . . . The fact that they were ganja smokers led me to believe that these effects were due to ganja . . I have no recollection of ever treating any case of dysentery, bronchitis, or asthma caused by ganja. *These cases are the basis of my remarks.* I do not remember any case of dysentery, bronchitis, or asthma in a ganja smoker which I attributed to any other cause. In other words, when I saw ganja smokers suffering from these diseases, I attributed them to ganja. *This was twenty years ago,* before I was a medical student." Pyari Sankar Dass Gupta, L.M.S. (witness No. 134), is a private medical practitioner, Secretary to the Bogra Medical Society of ten members, and a member of a temperance association founded by the late Keshub Chunder Sen. The witness is pledged against the use of all intoxicants. The witness submitted three papers to the Commission which seem to illustrate the development of tradition into opinion. In one paper the witness states: "The smokers of ganja often suffer from hoarseness of voice produced by the continual inhalation of its fumes, giving rise to sore-throat, bronchitis, and carbonaceous phthisis. It has long been a [illegible]*dition* in our country that the *ganja-khors always* die of dysentery, their intestines gradually sloughing [illegible]ay." In his second paper the witness states "Ganja smokers generally die of bloody dysentery, asthma and phthisis, and haemoptysis." And in his last paper he says: "It produces bloody dysentery and chest diseases, blood spitting, bronchitis, asthma, and phthisis." Kailas Chundra Bose, L.M.S. (witness No. 135), is a private medical practitioner in Calcutta with an extensive practice. He states that no ill effects are produced by the moderate use, and that, instead of causing bronchitis, dysentery, or asthma, it relieves these afflictions. The witness, however, states in his oral examination: "My experience is not to any large extent what I have gathered in my practice, but rather what I have learnt from smokers." Assistant Surgeon Akbar Khan (witness No. 124) is another Teacher in the Patna Medical School. He states the habitual moderate use of any of the drugs does not produce noxious effects, but that charas and ganja cause dysentery, bronchitis, and asthma if the consumers are not well fed. Witnesses Nos. 126 and 138 consider that no ill effects are produced. Assistant Surgeon Upendra Nath Sen (witness No. 118) states that bronchitis, and asthma are common complaints of ganja smokers. Madhab Krishna Dass, L.M.S. (witness No. 158) a private practitioner in Calcutta, considers that smoking may cause dysentery, bronchitis, or asthma. Assistant Surgeon Durga

Nath Chakravarti (witness No. 150) considers that "ganja causes dysentery after a long run." Annoda Prasanna Ghatak, M.B. (witness No. 149), a private medical practitioner, considers that digestive complaints are caused when good food is not procurable. Rakhal Das Ghosh, L.M.S., (witness No. 149) a private practitioner in Calcutta, had apparently seen no ill effects caused by the drug. The remaining witnesses in this class clearly failed to discriminate between the moderate and excessive use and their evidence has not been considered.

Three hospital assistants were examined. One gave no reply regarding moderate use. The other stated: "The habitual moderate use of ganja or charas does not produce any noxious effects - physical, mental, or moral, but the use of ganja impairs the constitution in some way or other . . . and has a tendency toward bronchitis

and asthma." Witness No. 145 is a vernacular class hospital assistant, but not now in Government employ. According to this witness, moderate use of ganja leads to excessive use. "The habitual moderate consumers, as well as the excessive consumers, suffer in their lungs and become insane . . . No intoxicant can be taken in moderation except when administered medicinally."

Seven native practitioners were examined. Bijoya Ratna Son (witness No. 151), a kabiraj10 practising in Calcutta, considers that the habitual moderate use of ganja or charas, but not siddhi, may in some cases cause bronchitis, dysentery or asthma. Witness No. 152, also of Calcutta, gives the same reply couched in the same language. Witness No. 126, of Nattore, in the Rajsha-hi district, and witness No. 153, of Calcutta, both consider the moderate use harmless. Piyari Mohan (witness No. 154), a kabiraj states: "I know it causes dysentery and I believe owing to its healing power it can cause bronchitis and asthma." Kedareswar Acharjya (Witness No. 137) remarks: "Those ganja smokers who cannot command abundant wholesome food suffer from dysentery, but it is difficult to determine how far it is due to ganja or to improper food. As to asthma, I have not seen any typical case originating from ganja smoking. I know that a chronic catarrhal condition of the air passages with a certain amount of spasm is the misfortune of many old ganja smokers. I know a friend who suffered from chronic bronchitis, and in whom asthmatic fits were induced by attempts to smoke ganja." The witness refers also to another case in which a habitual ganja smoker had an asthmatic attack which subsided on breaking off the habit and reappeared on resuming it." This witness lays stress in personal idiosyncrasy as modifying the effects of the drugs, and on the importance of a diet rich in fat. Witness No. 155, another kabiraj, states that, while no ill effects are produced, occasionally it entices dysentery, bronchitis, and asthma. Witness No. 128, also a kabiraj, states that, according to the Aurveda Shastra, smoking these drugs causes bronchitis and asthma, and in his opinion "even the moderate use of any of these drugs, not according to the rules of Shastra, is injurious in its effects." This witness does not appear to have any personal knowledge of ill effects, but to base his views on the teachings of the Shastras. Witness No. 139 states: "Certainly they produce effects on the moral and physical constitution," but as the witness is silent as to the effects of excessive use, probably he has not discriminated between the two uses of the drugs. Witness No. 157, a valid11, considers that even the habitual moderate use of these drugs produces noxious effects. This is the pandit who was consulted by Dr. Flood Murray (witness No. 102), and who produced two cases of hemp drug asthma and weakened heart for Dr. Murray's inspection. These seem to have been the only cases in any way connected with hemp drug that he had. Witness No. 146 is a zamindar12 and medical practitioner, and does not reply as to effects. Witness No. 147 studied two and half years at the Calcutta Medical College, but took no degree. He states that no noxious effects are produced without giving details (1·205-8).

After reviewing similar conflicting testimony from the other states, the Commission concluded:

The medical evidence which has thus been analyzed very clearly indicates in the opinion of the Commission that when the basis of the opinions as to the alleged evil effects of the moderate use of the drugs is subjected to careful examination, the grounds on which the allegations are founded, prove to be in the highest degree defective. A large number of medical witnesses of all classes, ascribe dysentery, bronchitis, and asthma to the moderate use of the drugs. An equally representative number give a diametrically opposite opinion. The most, striking feature of the medical evidence is perhaps the large number of practitioners of long experience who have seen no evidence of any connection between hemp drugs and disease, and when witnesses who speak to these ill effects from the moderate use are cross-examined it is found that (a) their opinions are based on popular ideas on the subject; (b) they have not discriminated between the effects of moderate and excessive use of the drugs; (c) they have accepted the disease as being induced by hemp drugs because the patients confessed to the habit; and (d) the fact has been overlooked that the smoking of hemp drugs is recognized as a remedial agent in asthma and bronchitis. A few witnesses incidentally refer to personal idiosyncrasy as perhaps being a factor in rendering some consumers of the drugs less tolerant and more liable to be affected by them even when used in moderate quantity. This view the Commission are prepared to accept; but for the vast majority of consumers, the Commission consider that the evidence

shows the moderate use of ganja or charas not to be appreciably harmful, while in the case of moderate bhang drinking the evidence shows the habit to be quite harmless. As in long continued and excessive cigarette smoking considerable bronchial irritation and chronic catarrhal laryngitis may he induced, so, too, may a similar condition be caused by excessive ganja or charas smoking; and to the oetiology of bronchial catarrh and asthma in ganja smokers the Commission have already referred. The direct connection alleged between dysentery and the use of hemp drugs the Commission consider to be wholly without any foundation. In the case of bhang there is nothing in the physiological action of the drug which could in any way set up an acute inflammation of the large intestine resulting in ulceration. On the contrary, it is well known that hemp resin is a valuable remedial agent in dysentery. As regards ganja or charas smoking inducing dysentery, even assuming that the products of the destructive distillation of the drugs directly reached the intestines, there is evidence that those products, when condensed and injected into a cat's stomach, failed to induce any inflammatory process. The connection, therefore, between hemp drug smoking and dysentery appears even remoter than in the case of bhang drinking and that disease and cannot be accepted by any stretch of the imagination as even a possible direct cause of dysentery (1: 223).

7 214 Medical Officers, 34 Practitioners of European medicine and 87 Practitioners of native methods.

8 Learned man, teacher; esp., a Brahman versed in Sanskrit, and in the science, laws, and religion of the Hindus; in Kashmir, any clerk or native official.

9 In Moslem countries, a ruler or a judge.

10 A member of a Unitarian reform sect of India based upon the teachings of Kabir (Hindu mystic and poet, c. 1450-1518).

11 A native practitioner.

12 A land owner; also: Formerly, under the Mohammedan administration, a collector of the land revenue of a specified district for the government. Now, usually a kind of feudatory recognized as an actual proprietor so long as he pays the government a fixed revenue averaging in different provinces less than one-half the net revenue (India).

Cannabis and Insanity

Because many people believed that the use of hemp drugs led to insanity, especially in the case of prolonged use of large amounts of charas and perhaps ganja, the Commission addressed a significant amount of effort to the study of this topic (1: 225 and all of Vol. 2). In addition to the testimony received from physicians, the Commission set about to evaluate all cases admitted to the Indian mental hospitals for the year 1892 that were listed as being caused by hemp drugs (1:227).

Initial inquiry into the Dullunda Asylum at Calcutta led the Commission to distrust the asylum statistics. Because of incomplete figures, frequent absence of supporting data and outright errors, the Commission decided to take up each of the cases of 1892 separately and to inquire as fully as possible into its history (1:227).

In the course of its inquiry into the 24 asylums in India and Burma, the Commission sharply criticized the testimony of the reporting superintendents:

They have known nothing of the effects of the drugs at all, though the consumption is so extensive, except that cases of insanity have been brought to them attributed with apparent authority to hemp drugs. They have generalized from this limited and one-sided experience. They have concluded that hemp drugs produce

insanity in every case, or in the great majority of cases, of consumption. They have had no idea that in the vast majority of cases this result does not follow the use. They have accordingly without sufficient inquiry assisted, by the statistics they have supplied and by the opinions they have expressed, in stereotyping the popular opinion and giving it authority and permanence (1:226).

With such hindrances to the inquiry into the connection between hemp drugs and insanity, the Commission, after careful inquiry into the 222 cases allegedly attributed to hemp drugs, from among the total of 2,344 patients admitted during the year 1892 to asylums, concluded, with reservation, that some 61 cases might have been caused by hemp drugs alone:

Even in regard to the remaining 61 cases, it must be borne in mind that it is impossible to say that the use of hemp drugs was in all the sole cause of insanity, or indeed any part of the cause. The following considerations combine to demand caution and reserve in pronouncing an opinion on this point.

Firstly, there are twelve cases in which it has been found impossible to obtain any further information by local inquiry. In these cases we are thrown back on the original papers and the asylum history. Besides these, there are ten more cases in which the patients are beggars and foreign laborers about whose past history no satisfactory information is obtainable. Thus there remain only 39 of these 61 cases about which anything like a satisfactory inquiry has been possible. Further, a great majority of these cases come from the lower orders of cultivators and laborers, from whom information of any value is very difficult to obtain as to other than the most apparent causes. The fact of the existence of the hemp habit is easy enough to ascertain, but that it is the cause, or one of the causes of the insanity, or that it even preceded the insanity, is much more difficult to establish.

Secondly, the method of inquiry has not been satisfactory in regard to all the cases referred for local inquiry. In regard to the great majority, the instructions issued by the Commission as to the agency by which this further inquiry should be conducted have been carried out. But in some, it will be observed, even this further inquiry has been left to the police. Then again there are cases, such as those of the Hyderabad (Sind) Asylum, in which the Superintendent has necessarily been the principal agent in the inquiry, and has, perhaps, not unnaturally but certainly unfortunately, evinced a strong tendency to defend the old asylum entries regarding cause. The series of questions framed by the Civil Surgeon of Delhi for use in the further inquiry also illustrates a tendency to assume that the cases were hemp drug cases, and thus to limit the scope of the inquiry.

Thirdly, it may be noted that excess in the use of hemp drugs is very frequently only one of several vices in which a dissipated man indulges. Further inquiry has proved this in several cases. There is strong probability that had information been complete, it would have been established in many more cases. It is impossible in such cases to say definitely to what form of excess insanity may be mainly due. Further, it is an accepted and established fact that intemperance of any kind may sometimes be not the cause of insanity, but an early manifestation of mental instability. Dr. Conolly Norman (Hack Tuke's Dictionary of Psychological Medicine: article "Mania") says: "The patient also indulges in intoxicants with very undue or unwonted freedom, and thereby precipitates the course and aggravates the symptoms of his disease." One or two cases have been rejected by the Commission on the ground that the evidence merely showed that the habit of use of hemp began at the same time as the mental aberration, or even later. There may have been other cases in which this would have been shown had the information been complete. It is possible therefore that more complete information might have shown in some cases, not only that other causes contributed to the insanity, but also that hemp drugs had nothing whatever to do with inducing it.

These and similar considerations already indicated demand caution in the expression of any judgment as to the causation of insanity in this country. If in England opinion, based on inquiries such as are there possible, has to be stated with caution, this is much more necessary here. In many or the cases in which the hemp

drug habit has been established, it is impossible to feel certain in view of the defective character of the information that the drugs have been the sole cause, or perhaps indeed a cause at all, of the insanity (1:241-2).

Summing up, the Commission indicates the difficulties that prevent conclusive answers to the question of causality between the use of hemp drugs and insanity:

In answering the question therefore, on what the evidence rests that hemp drugs may induce mental aberration, the Commission would offer the following remarks: The evidence may he considered under two heads - (a) popular; (b) scientific. The popular idea that the use of hemp drugs may induce insanity can be traced back for many centuries, and the present day views on the subject are no doubt the outcome of old popular ideas which have been handed down and become concrete. With non-medical wit the mere use of the drug along with the fact of insanity, as the evidence shows, has as a rule been accepted as cause and effect. Of the large number of medical witnesses who have given evidence before the Commission, probably not a single one has ever observed the inception of the habit and the use giving rise to mental aberration, and been in a position to gauge the value of other contributory causes if present. With practically no modern literature on the subject, with no special knowledge apart from the popular idea, with a very slight or no clinical experience of insanity in England, with the experience derived from perhaps having had half a dozen insanes in the course of two years under observation as Civil Surgeons, officers have been placed in charge of asylums, and have had to differentiate between cases of hemp drug insanity and ordinary mania. The careful inquiry which has been made by the Commission into all the alleged hemp drug cases admitted in one year into asylums in British India demonstrates conclusively that the usual mode of differentiating between hemp drug insanity and ordinary mania was in the highest degree uncertain, and therefore fallacious. Even after the inquiry which has been conducted, it cannot be denied that in some of the cases at least the connection between hemp drugs and insanity has not been conclusively established (1:250).

Thus, final answers to this pressing but complex question of the causal relation between hemp drugs use and insanity, as such, remain obscured.

With their usual thoroughness, the Commission sought to explore the possible structural changes to the brain caused by chronic hemp drugs use. Because data from neuropathologic studies based on postmortem examinations was wholly lacking, Brigade-Surgeon-Lieutenant-Colonel D.D. Cunningham, F.R.S., C.I.E., undertook three experiments at the Biological Laboratory attached to the Zoological Garden in Calcutta to evaluate the effects following the continued administration of hemp drugs to monkeys (3:192-6).

The first study dealt with the chronic smoking of ganja in a 16 lb. male rhesus monkey. By means of a smoking chamber, the animal was administered 181 inhalations of ganja smoke over a period of about 8 1/3 months. The daily dose was supplied by a habitué, the amount administered being proportional by weight to that consumed daily by the chronic user. An autopsy performed after sacrificing the animal, including gross examination of the brain, revealed an absence of any pathology.

The second experiment examined the effects of chronic oral ingestion of charas, with the daily dose again obtained from a chronic user on a comparative weight basis. The animals used this time were two smaller *cynomolgus* monkeys, weighing 5 lb. 7 oz. and 4 lb. 1oz. The study lasted 67 days, the animals receiving the drug mixed in milk on 62 days. Because either minimal or no effects were noted, the dose was increased from the usual 1/2 grain to 2 and then 3 grains about a week before termination of the study. Although no behavioral effects were noted with this higher dose schedule, the animals refused to eat the charas-treated milk after three days, bringing the study to a premature end. These animals were not sacrificed.

The third investigation evaluated the effects on a rhesus monkey of the smoking of dhatura daily, for six weeks. The same inhalation chamber was used as in the first experiment. Unfortunately the size of the dose

is not specified. Post-mortem examination of the central nervous system revealed the following effects:

On opening the cranium the dura-mater was found to be somewhat thickened and, especially in the neighbourhood of the superior longitudinal sinus, very conspicuously congested. In this region, too, the membrane in the occipital region was fixed to the cranial walls by soft, very vascular adhesions. The pia-mater was thickened and so highly injected throughout that the cerebral surface had a generally diffused pink tint. The cerebral substance was everywhere abnormally soft and so friable as to render any immediate removal of the membranes impossible without the occurrence of much destruction of the nervous tissue. Like the surface, although in minor degree, it was of a pinkish tinge owing to abnormal accumulation of blood. Conditions or this kind appeared to be universally diffused throughout the whole of the cerebral centres, the texture of the hemispheres, of the cerebellum and of the basal ganglia being alike soft, and the evidence of abnormal congestion universally distributed. In spite of this, however, the spinal cord and its membranes were to all appearance perfectly healthy.

In so far as a single experiment goes the results in this case would, then, seem in show that the habitual inhalation of the smoke of dhatura, even when only practised for a relatively brief period, is sufficient to establish serious morbid changes in the cerebral nervous centres, and that it therein differs from the habitual inhalation of the smoke of ganja extending over a much more prolonged period. This clearly indicates the necessity of distinguishing between cases in which ganja alone is employed from those in which a mixture of ganja and dhatura is substituted for it, as otherwise certain prejudicial effects which are really due to the use of the latter drug may be erroneously credited to the former one" (3:195-6).

Comparisons made concerning organic brain pathology caused by alcohol (whose effects were well known from other studies) and dhatura left the Commission with the impression that these other Intoxicants were far more hazardous than hemp drugs:

So far as the information from all sources before the Commission is concerned there is no evidence of any brain lesions being directly caused by hemp drugs, as they have been found to be caused by alcohol and dhatura; and there is evidence that the coarse brain lesions produced by alcohol and dhatura are not produced by hemp drugs (1.251).

The complex phenomenon of intoxication, as such, was noted by the Commission:

The individual factor with its idiosyncrasies plays here, as everywhere, a very important part. There are other factors, too, which have to be considered, the degree of education, reason, locality, dosage, and mode of preparation of the drug, all of which may modify the symptoms. Thus the hallucinations of the Western people under the influence of hashish are not identical with the voluptuous dreams of the Orientals (1:253).

Of more functional import is the discussion of medico-legal questions involved in the confusion between intoxication and insanity:

A more serious result of this confusion is that there are cases in which men who have committed offenses, especially crimes of violence, under the influence of hemp drugs have been acquitted on the ground of insanity, although the circumstances have been such that had the intoxicant been alcohol, they would have been convicted. It is undoubtedly more difficult in the case of ganja than in the case of alcohol to recognize the line drawn for social and legal purposes between intoxication and insanity. But the difficulty is not insuperable. The main reason for the confusion that has existed is probably the ignorance that has prevailed regarding hemp drugs. When they are recognized as a common intoxicant, it is to be hoped that the practice of the Courts will be freed from the occasional blemishes above indicated. It is not expedient nor is it just that intoxication from hemp drugs should secure immunity from punishment which is not allowed to alcohol (1:254).

Cannabis and Crime

The use of hemp drugs had been implicated as a cause of crime:

Discussing the connection of hemp drugs with crime, it is necessary to discriminate between any effect which they may be supposed to produce of crime in general and the unpremeditated crimes of violence to which intoxication may give rise. Thus there are those who allege that the habitual use of alcohol, at all events if carried to excess, degrades the mind and character of the consumer and predisposes him to crime in general, or to crimes of particular character, especially to offenses against property. Drink is thus so down sometimes as one of the most efficient agencies for increasing the criminal classes. On the other hand, there are well known cases in which intoxication from alcohol has led to crimes of an occasional and exceptional character generally to unpremeditated crimes of violence or other unpremeditated offenses against the person. These two classes of cases should be carefully distinguished and treated separately (1:253-6).

In addition to hearing testimony of numerous enforcement and county officials, the Commission examined the 81 case records of crimes of violence alleged to have been caused by cannabis drugs in the whole of India over the prior 20 years. The Commission immediately excluded 5 of these cases, ascertaining either that data included in abstracts of the court records did not support the assertion that hemp drugs were causative factor, or that the records were unavailable.

In each of the remaining 23 cases, the Commission reviewed the court transcripts and examined, where possible, individuals who were connected, with the case (1:259-60; 3:262-6). The Commission concluded:

Of these twenty-three cases, then, the records in not less than eighteen show that the crimes cannot be connected with hemp drugs. There is one case of which doubt is thrown by subsequent discoveries. The connection between drugs and crime is only established in the remaining four. It is astonishing to find how defective and misleading are the recollections which man witnesses retain even of cases with which they have had special opportunities of being well acquainted. It is instructive to see how preconceived notion based on rumour and tradition tend to preserve the impression of certain particulars, while the impressions of far more important features of the case are completely forgotten.

In some cases these preconceived notions seem to prevail to distort the incident altogether and to create a picture in the mind of the witness quite different from the recorded facts. Some of the witnesses whose me have thus failed them are men who might have been expected to be careful and accurate. Their failure must tend to increase the distrust with which similar evidence, which there has been no opportunity of testing must be received (1:263).

On the topic of crime, the Commission concluded:

In respect to his relations to society, however, even the excessive consumer of hemp drugs is ordinarily inoffensive. His excesses may indeed bring him to degraded poverty which may lead him to dishonest practices; and occasionally, but apparently very rarely indeed, excessive indulgence in hemp drugs may lead to violent crime. But for all practical purposes it may be laid down that there is little or no connection between the use of hemp drugs and crime (1:264).

Conclusions

The Commission have now examined all the evidence before them regarding the effects attributed to hemp drugs. It will be well to summarize briefly the conclusions to which they come. It has been clearly established that the occasional use or hemp in moderate doses may be beneficial: but this use may be

regarded as medicinal in character. It is rather to the popular and common use of the drugs that the Commission will now confine their attention. It is convenient to consider the effects separately as affecting the physical, mental, or moral nature.

Physical Effects

In regard to the physical effects, the Commission have come to the conclusion that the moderate use of hemp drugs is practically attended by no evil results at all. There may be exceptional cases in which, owing to idiosyncrasies of constitution, the drugs in even moderate use may be injurious. There is probably nothing the use of which may not possibly be injurious in cases of exceptional intolerance. There are also many cases where in tracts with a specially malarious climate, or in circumstances of hard work and exposure, the people attribute beneficial effects to the habitual moderate use of these drugs; and there is evidence to show that the popular impression may have some basis in fact. Speaking generally, the Commission are of opinion that the moderate use of hemp drugs appears to cause no appreciable physical injury of any kind. The excessive use does cause injury. As in the case of other intoxicants, excessive use tends to weaken the constitution and to render the consumer more susceptible to disease. In respect to the particular diseases which according to a considerable number of witnesses should be associated directly with hemp drugs, it appears to be reasonably established that the excessive use of these drugs does not cause asthma; that it may indirectly cause dysentery by weakening the constitution as above indicated; and that it may cause bronchitis mainly through the action of the inhaled smoke on the bronchial tubes (1:263-4).

Mental Effects

In respect to the alleged mental effects of the drugs, the Commission have come to the conclusion that the moderate use of hemp drugs produces no injurious effects on the mind. It may indeed be accepted that in the case of specially marked neurotic diathesis, even the moderate use may produce mental injury. For the slightest mental stimulation or excitement may have that effect in such cases. But putting aside these quite exceptional cases, the moderate use of these drugs produces no mental injury. It is otherwise with the excessive use. Excessive use indicates and intensifies mental instability (1:264).

Moral Effects

In regard to the moral effects of the drugs, the Commission are of opinion that their moderate use produces no moral injury whatever. There is no adequate ground for believing that it injuriously affects the character of the consumer. Excessive consumption, on the other hand, both indicates and intensifies moral weakness or depravity (1:264).

Discussion

Viewing the subject generally, it may be added that the moderate use of these drugs is the rule, and that the excessive use is comparatively exceptional. The moderate use practically produces no ill effects. In all but the most exceptional cases, the injury from habitual moderate use is not appreciable. The excessive use may certainly be accepted as very injurious, though it must be admitted that in many excessive consumers the injury is not clearly marked. The injury done by the excessive use is, however, confined almost exclusively to the consumer himself; the effect on society is rarely appreciable. It has been the most striking feature in this inquiry to find how little the effects of hemp drugs have obtruded themselves on observation. The large number of witnesses of all classes who professed never to have seen these effects, the vague statements

made by many who professed to have observed them, the very few witnesses who could so recall a case as to give any definite account of it, and the manner in which a large proportion of these cases broke down on the first attempt to examine them, are facts which combine to show most clearly how little injury society has hitherto sustained from hemp drugs (1:264).

REPORT OF THE INDIAN HEMP DRUGS COMMISSION, 1893-94.

President:

The Hon'ble W. MACKWORTH YOUNG, M.A., C.S.I., First Financial Commissioner, Punjab.

Members:

1. Mr. H.T. OMMANNEY, Collector, Panch Mahals, Bombay.

2. Mr. A. H. L. FRASER, M.A., Commissioner, Chhattisgah Division, Central Provinces.

3. Surgeon-Major C.J.H. WARDEN, Professor of Chemistry, Medical College, and Chemical Examiner to Government, Calcutta; Officiating Medical Storekeeper to Government, Calcutta.

4. Raja SOSHI SIKHARESWAR ROY, of Tahirpur, Bengal.

5. KAHWAR HARNAN SINGH, Ahluwalia, C.I.E., Punjab.

6. LALA NIHAL CHAND, of Muzaffarnagar, North-Western Provinces.

Secretary:

Mr. H.J. McINTOSH, Under-Secretary to the Government of Bengal, Financial and Municipal Departments.

SIMLA:

PRINTED AT THE GOVERNMENT CENTRAL PRINTING OFFICE.

1894.

Price Rs. 3.

Period of Attendance with the Commission

Name

(a) During the first tour

(b) During the second tour

(c) Number of meetings for examination of witnesses attended

- **President**

(a) 83 days

(b) 183 days

(c) 86

- **Mr. Ommanney**

(a) 83 days

(b) 183 days

(c) 85

- **Mr. Fraser**

(a) 83 days

(b) 193 days

(c) 85

- **Dr. Warden**

(a) 83 days

(b) 183 days

(c) 86

- **Raja Soshi Sikhareswar Roy**

(a) From 3rd August to 15th September, 44 days

(b) From 30th October to 24th January, from 14th to 16th February, from 22nd to 24th February, and from 7th to 25th March, 112 days

(c) 44

- **Kanwar Harnam Singh**

(a) 83 days

(b) From 13th November to 5th January, 22nd February to 2nd April, and from 12th to 25th April, 78 days

(c) 48

CORRECTION

THE FOLLOWING DOCUMENT(S)
HAVE BEEN REFILMED TO
ASSURE LEGIBILITY OR PAGINATION

- **President**

(a) 83 days

(b) 183 days

(c) 86

- **Mr. Ommanney**

(a) 83 days

(b) 183 days

(c) 85

- **Mr. Fraser**

(a) 83 days

(b) 193 days

(c) 85

- **Dr. Warden**

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(c) 44

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(a) 83 days

(b) From 13th November to 5th January, 22nd February to 2nd April, and from 12th to 25th April, 78 days

(c) 48

Lala Nihal Chand

(a) 3rd August to 20th September, 49 days

(b) From 30th October to 18th November and from 17th to 25th April, 29 days

(c) 5

The attendance of Raja Soshi Sikhareswar Roy was broken by occasional absence caused by ill-health and other reasons. The absence of Kanwar Harnam Singh during two short periods was due to ill-health. The prolonged absence of Lala Nihal Chand was due to the fact that he suffered from continued ill-health, and was able to be with the Commission only at Calcutta at the first; then for some part of their preliminary tour and at a few meetings for the examination of witnesses during the second tour. All the members were present at Simla during the preparation of the report (1:11).

POLICY FOR THE NEW MILLENNIUM:

WORKING TOGETHER TO REDEFINE CANADA'S DRUG STRATEGY

REPORT OF THE SPECIAL COMMITTEE ON NON-MEDICAL USE OF DRUGS

Paddy Torsney, M.P.
Chair

December 2002

CHAPTER 9: CANNABIS

1. MANDATE OF THE SPECIAL COMMITTEE ON NON-MEDICAL USE OF DRUGS

As explained in Chapter 1, the Special Committee on Non-Medical Use of Drugs was initially mandated to study "the factors underlying or relating to the non-medical use of drugs in Canada" and to bring forward recommendations aimed at reducing "the dimensions of the problem involved in such use." That mandate was expanded on 17 April 2002 when the House of Commons, by order of reference, added the subject matter of Private Member's Bill C-344, *An Act to amend the Contraventions Act and the Controlled Drugs and Substances Act (marihuana)*.[299] This chapter will consider the provisions of the *Controlled Drugs and Substances Act* (CDSA) only as it relates to the criminal prosecution of cannabis offences.[300]

Bill C-344 proposed to amend the *Controlled Drugs and Substances Act* and the *Contraventions Act*, to make the offences of possession, possession for the purposes of trafficking and trafficking in small amounts of cannabis (one gram or less of cannabis resin and thirty grams or less of cannabis (marijuana)) "ticketable" offences. The available penalties would be a $200 fine for a first conviction, $500 for a second and $1,000 for a third. At present, possession of those amounts is a summary conviction offence with a maximum penalty of a $1,000 fine or six months in jail, or both. Today, trafficking of anything less than 3 kg of cannabis resin or marijuana is exclusively indictable and carries a maximum penalty of 5 years less a day imprisonment.[301] In support of his bill, Dr. Martin argued that it would unburden the courts, save money, and free up police resources to combat more serious offences.

2. LEGISLATIVE OPTIONS

The Committee heard a wide variety of suggestions respecting the legal treatment of cannabis. Some recommended legalization, either regulated or unregulated. Others favoured some form of decriminalization that would create a non-criminal offence of possession, while still others preferred a more cautious approach that would retain present prohibitions, while introducing more and better diversion options as a way of avoiding some of the harms associated with prosecution. There were also those who favoured increased penalties, at least for trafficking offences, and a renewed commitment to the goal of abstinence. For their part, some health care professionals thought that more research into the effects of cannabis should be undertaken before amending the law, in order to bring better information to the debate, while others pointed out that the illegal status of cannabis has contributed to "a real resistance to conducting those sorts of studies."[302]

For the purposes of this discussion, the Committee defines *legalization* as the removal of all criminal sanctions prohibiting the production, sale or possession of a given substance. Legalization need not be accompanied by the removal of all regulatory controls. In fact, the ability to regulate production and supply, to tax, and to limit access by age, are often cited as major advantages of legalization. The Committee uses the term *decriminalization* to refer to the removal of *criminal* sanctions for certain activity while retaining legal prohibitions. Decriminalization would allow continued criminal prosecution of many or most actions relating to an illicit substance like cannabis, while allowing possession of small amounts of the same substance for personal use to be treated as a regulatory offence, with consequences not unlike those attached to minor motor vehicle infractions under provincial legislation. Under such a scheme, prosecution of the new regulatory offence could be initiated by issuance of a ticket, fines could be paid without a court appearance, and enforcement would not result in a criminal conviction.

The Committee heard from witnesses who expressed the view that the prosecution of cannabis-related offences takes up too much of our scarce criminal justice resources. The potentially negative impact of a criminal conviction was often given as another reason for changing the law. The possibility of uneven or inconsistent enforcement of existing laws may also lend support for legislative changes, to ensure that some individuals don't end up with a large fine and a criminal conviction for possession of a small amount, while others are simply warned and/or have their cannabis confiscated. Although some witnesses argued that enforcement agencies no longer target cannabis possession, preferring instead to pursue more serious CDSA charges, recent crime statistics make clear that possession still constitutes the majority of cannabis incidents reported. For example, Statistics Canada noted that cannabis accounted for about three-quarters of all 91,920 drug-related incidents reported by Canadian police services in 2001. Moreover, 70 percent of those cannabis incidents were for possession.[303]

The following arguments are often made in support of legalization:

- criminal sanctions that do not have the support of a strong majority of the population lead to a loss of respect for the law and those responsible for enforcing it;
- the illicit status of cannabis results in users being exposed to traffickers who also deal in more harmful substances (the need for "separation of markets" has been cited as a principle reason for the existing cannabis policy in the Netherlands);[304]
- legalization also permits regulation and taxation, along with the ability to limit access on the basis of age.

On the other hand, the following reasons are most commonly cited by those who are opposed to legalizing cannabis;

- removing prohibitions would send the wrong message by normalizing use, especially for young people.[305] As an example, many argue that the current publicity around medical use of marijuana has already been perceived by some as an endorsement of the healthful effects of the drug;
- cannabis acts as a "gateway" to the use of other more harmful drugs, if not directly through dependency, then indirectly, through the social milieu and risk-taking aspects of the behaviour.[306]

A majority of members of the Committee are persuaded that there is a need to reform the legislation respecting cannabis, for a variety of reasons. We agree, for example, that because enforcement of the law appears to be sporadic, uneven, and subject to regional discrepancies, its application is likely to be inconsistent and unfair. We further agree that the consequences of a criminal conviction for simple possession of a cannabis product are disproportionate to the potential harms associated with personal use. This is especially true when one considers the harm caused every day by the use of licit substances like tobacco, alcohol, and some common non-prescription medications.

However, the Committee shares the concern expressed by many educators, treatment providers, and law enforcement officers to name only a few, that many Canadians, and youth in particular, might misperceive legalization as evidence that Parliament is not concerned about the widespread use of cannabis. At least as far as this Committee is concerned, nothing could be further from the truth. Indeed, the Committee was told by various health care professionals, addictions specialists and treatment providers that frequent and prolonged use of cannabis can lead to dependence as well as social problems for certain users. In addition, Dr. Mark Zoccolillo expressed concern about the frequency of marijuana use among students he studied, the resulting potential for the disruption of short-term or "working memory," and the long-term consequences for that particular age group. Furthermore, the Committee is not convinced that legalization accompanied by regulation would remove the profit from the illegal production and sale of cannabis or in any significant way discourage criminals currently involved in distribution.

For those reasons, the Committee would prefer to see cannabis offences retained in the